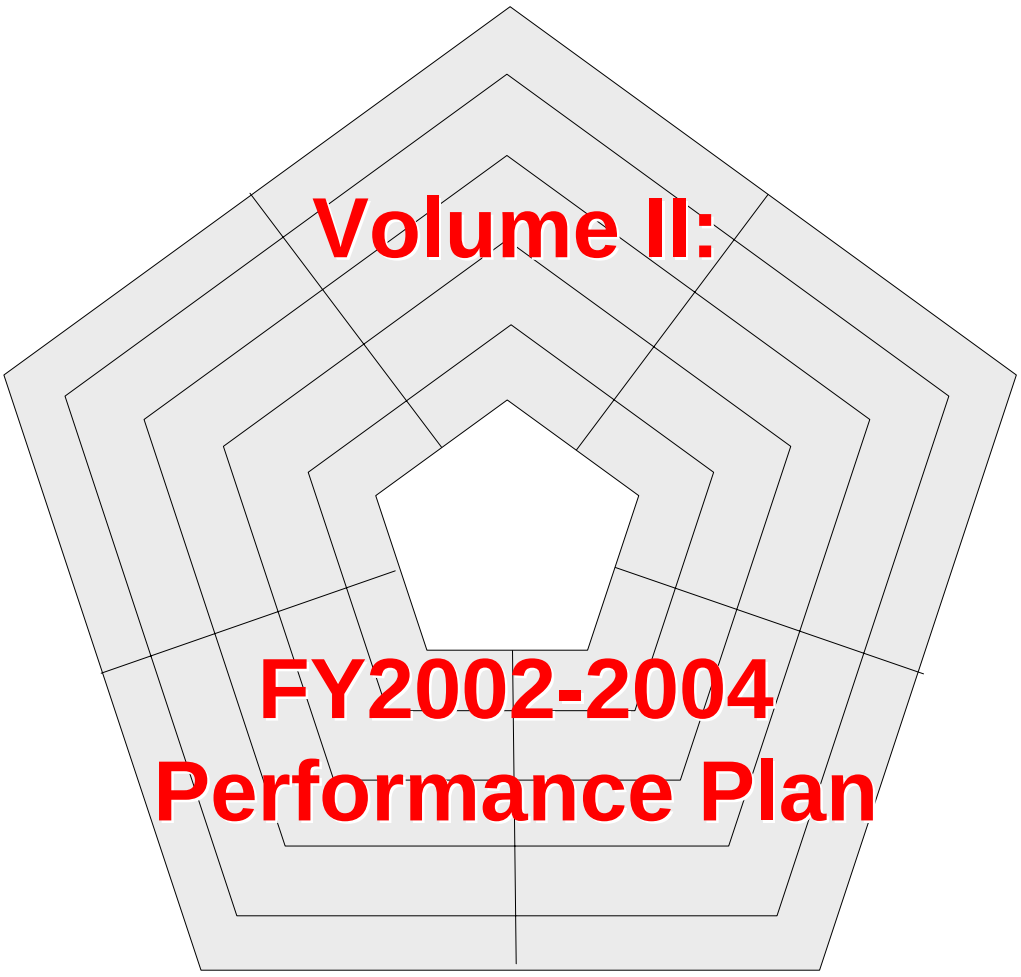
Department of Defense Chemical and Biological Defense Program



Volume II:

FY2002-2004 Performance Plan

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DoD CBDP Performance Plan – Contents

Section **Page**

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1.0 INTRODUCTION

This volume of the Department of Defense (DoD) Chemical and Biological Defense Program (CBDP) Annual Report to Congress provides a performance plan and assessment for the period FY02–FY04. This performance plan demonstrates compliance with the requirements of the Government Performance and Results Act (GPRA), which requires agencies to submit an annual performance plan to Congress. This plan establishes a *process* by which the CBDP can measure the effectiveness of the various projects under the CBDP and assessing their contributions to the operational goals and the mission of the program. This process provides a tool for identifying strengths and weaknesses in the development and execution of programs. This plan also is a reference document to aid in the effective oversight and management of the program.

The plan serves the purpose of providing an assessment of the performance of the most recently completed fiscal year (FY02) and provides the performance targets against which activities conducted during FY03 and FY04 will be assessed.

For FY02, the cumulative procurement targets identified are interim planning figures that reflect the evolving strategy to the force planning structure described in the 2002 Defense Planning Guidance. The DoD Chemical and Biological Defense Program is in the process of identifying specific system requirements to support new Defense Planning Guidance. The force planning construct that had been based on the quantities required to support two nearly simultaneous Major Theater Wars (MTWs) has been replaced. Defense Planning Guidance published subsequent to this review outlines a new force planning construct, known as the 4-2-1 force planning construct. This force planning construct is based on capabilities to deter forward in four critical areas, swiftly defeat aggression in two overlapping major conflicts, and winning decisively in one, while defending the United States homeland.[1] The Joint Staff and others are conducting assessments to determine how this change affects the procurement quantities to support warfighting requirements. Moreover, the assessment for the total acquisition objective will include a determination of the quantities required to support other than warfighting requirements, including requirements for industrial base, peacekeeping, training, homeland security, or other operations. The JRO is developing interim requirements based on the 4-2-1 construct for the Services' planning purposes. Since the Services have not had adequate opportunity to assess the impact of the 4-2-1 construct on their requirements, the JRO has recommended in the interim that 2 Major Combat Operations (MCO) requirements (equal to the existing 2 MTW requirements) be utilized until new requirements are determined. These recommendations are the basis of the assessments in this volume.

1.1 OVERVIEW OF PERFORMANCE PLAN

The DoD CBDP has prepared this performance plan to align itself more closely with the tenets of the Government Performance and Results Act (GPRA). Specifically, the plan:

- Establishes explicit and outcome-oriented goals linked to warfighters' ability to survive, fight, and win in a CB environment;
- Identifies quantitative and/or qualitative performance measures that can be used to assess progress towards goal achievement;

[1] A detailed explanation of the Defense Planning Guidance 4-2-1 force planning construct is available in the *2002 Annual Defense Report* "Chapter 5" (pp. 49-64) available at http://www.defenselink.mil/execsec/adr2002/pdf_files/chap5.pdf

- Describes how performance data is validated;
- Describes how RDT&E activities of participating DoD and non-DoD organizations are coordinated to achieve program goals; and
- Identifies human capital, financial, and resource challenges or external factors that limit the ability of the program to achieve its goals.

The performance plan draws on information and consolidates data from reports and plans already being prepared, including:

(1) the Modernization Plan,
(2) the Research, Development, and Acquisition (RDA) Plan,
(3) the Logistics Support Plan,
(4) the Joint Warfighting Science and Technology Plan,
(5) the Defense Technology Area Plan,
(6) the Annual Report to Congress, and
(7) President's Budget Submissions for the DoD CB Defense Program.

In addition, the performance plan draws on current data contained in documents prepared in support of the PPBS, including Defense Planning Guidance, the CBDP Program Strategy Guidance, the Program Objectives Memorandum, the President's Budget and supporting detailed information in the RDT&E and Procurement Congressional Justification Books.

The major portions of this performance plan link performance goals with performance measurements in terms of those systems and programs, which support the warfighter requirements and goals. **Section 1** provides the vision, mission, goals and performance measures for the CBDP. **Section 2** analyzes performance goals and measurements that support the advanced development and acquisition phases of CB defense systems in support of *Corporate Goal 1*. **Section 3** analyzes the science and technology base of the program to include basic and applied research and advanced technology development, which support essential capabilities meeting warfighter requirements in support of *Corporate Goal 2*. **Section 4** analyzes management practices in support of *Corporate Goal 3*: Oversee DoD CB defense modeling and simulation efforts and *Corporate Goal 4*: Improve DoD CB defense management practices – become a high performance organization. Performance goals, which support each corporate level goal of the CBDP, establish a measurable path to incremental achievement of specific goals. These performance goals are supported and evaluated by measurable outputs, which are assessed using performance measures. Performance measures quantify the output of the CB defense program for key measures associated with providing a ready force, capable of conducting operations in CB contaminated environments.

1.2 VISION, MISSION, AND VALUES OF THE CBDP

Ensure that the Department of Defense has a world class CBRN defense capability that addresses all current and future threats to warfighter and homeland security missions.

Figure 1. Chemical and Biological Defense Program Vision

This vision statement provides focus and direction to chemical and biological defense research, development, and acquisition efforts within the CBDP. The vision statement for the CBDP has been revised to reflect changes in the national security strategy that have occurred as a

result terrorist attacks of September 11, 2001 and the anthrax-contaminated letters in 2001. While the principal focus of the CBDP vision is on threats to the warfighter, the vision recognizes the increasing role and importance that DoD personnel and assets will play in support of missions that have not been the traditional domain of the military, namely, DoD support to homeland security. A key aspect of DoD's role in homeland security is a recognition that DoD will support and rely on other federal agencies, as well as state and local emergency responders and private organizations in response to terrorist and others threats to the U.S. homeland.

The *Department of Defense Annual Report to the President and the Congress*, 2002 outlines the paradigm shift in force planning that resulted from changes outlined in the *Quadrennial Defense Review*, September 2001. FY02 requirements are based on supporting the "4-2-1" Force Planning Construct. The 4-2-1 Force Planning construct replaces the previous force planning construction of two nearly simultaneous Major Theater Wars (MTWs).

This new force planning construct calls on DoD to maintain regionally tailored forces forward deployed and stationed in *four (4)* critical regions to assure allies, counter coercion and deter aggression against the United States, its allies, and its friends. U.S. forces will remain capable of undertaking major combat operations (MCOs) on a global basis and will train to be effective across a wide range of combat conditions and geographic settings. For planning purposes, U.S. forces will remain capable of rapidly transitioning from its steady-state condition to conducting of an effects-based campaign that aims at swiftly defeating attacks against U.S. allies and friends in any *two (2)* theaters of operation in overlapping timeframes. U.S. forces will retain the capability to decisively defeat an adversary in *one (1)* of the two theaters in which U.S. forces are conducting major combat operations, including the ability to occupy territory or set the conditions for a regime change if so directed by the President. In addition, the new planning approach requires the United States to maintain and prepare its forces for smaller-scale contingency operations in peacetime, preferably in concert with allies and friends.

In order to support the 4-2-1 force-sizing construct and to implement to program vision, **Figure 2** defines the mission for the Chemical and Biological Defense Program. Over the next year, the Department will review this mission and the supporting operational goals to address its evolving role in combating terrorism and homeland security. As noted in the Volume 1, The DoD CBDP Annual Report, the specific equipment requirements to support the 4-2-1 force-sizing construct are in the process of being defined. Interim draft planning figures are provided in Chapter 3 and Annex F of the Annual Report as well as portions of this performance plan. These planning figures will be revised for the next year's report.

Ensure that the U.S. military has the capability to operate effectively and decisively in the face of chemical, biological, radiological or nuclear (CBRN) threats in warfighter missions (passive defense, force protection, and consequence management) and homeland security missions. Advance national interests within the CBRN defense arena by working effectively with other federal agencies, state and local governments, Congress, and the private sector.

Figure 2. Chemical and Biological Defense Program Mission

A key element in providing a means to establish progress in fulfilling the program mission is the definition of corporate goals for the CBDP, as shown in **figure 3**. Corporate goals provide the broad warfighter requirements for NBC defense operations. These operational goals

provide direction for the development, acquisition, and fielding of NBC defense equipment. The CBDP thus develops, acquires, and fields equipment that meets warfighter requirements while reducing acquisition costs and time of development. Figure 3 defines the corporate operational goals (and provides a summary of the key materiel capabilities that support these goals.)

- **Goal 1: Develop CB defense capabilities to meet Joint Acquisition Objectives at reduced costs and on schedule.**
- **Goal 2: Develop and support a science and technology base program that integrates the DoD and other Federal Agency CB defense research efforts.**
- **Goal 3: Oversee DoD CB defense modeling and simulation efforts.**
- **Goal 4: Improve DoD CB defense management practices – become a high performance organization.**

Figure 3. Chemical and Biological Defense Program Corporate Goals

Chemical/Biological Defense Program Values

In order to carry out the mission of the CBDP, criteria and processes to guide the methods in which the goals and mission will be pursued have been defined. As stated in the Quadrennial Defense Review (QDR) report, the general policy objectives of the Department of Defense, which are to:

(1) assure allies and friends,
(2) dissuade future military competition,
(3) deter threats and coercion against U.S. interests, and
(4) if deterrence fails, decisively defeat any adversary.

These policy objectives are described in detail in the QDR Report. These defense policy goals are supported by an interconnected set of strategic tenets. It is only through careful attention and commitment to each of these tenets that the defense policy goals will be achieved. These tenets comprise the essence of U.S. defense strategy, and include:

- *Managing risks* — DoD must prepare for future challenges over time, while meeting extant threats at any given time.
- *A capabilities-based approach* — focuses more on how an adversary might fight than who the adversary might be and where a war might occur. It broadens the strategic perspective and requires identifying capabilities that U.S. military forces will need to deter and defeat adversaries who will rely on surprise, deception, and asymmetric warfare to achieve their objectives.
- *Defending the United States and Projecting U.S. Military Power* — restores the emphasis once placed on defending the United States and its land, sea, air, and space approaches.
- *Strengthening Alliances and Partnerships* — requires that U.S. forces train and operate with allies and friends in peacetime as they would operate in war.

- *Maintaining favorable regional balances* — secure peace, extend freedom, and assure its allies and friends.
- *Developing a broad portfolio of military capabilities* — to create substantial margins of advantage across key functional areas of military competition to prevail over current challenges and to hedge against and dissuade future threats.
- *Transforming defense* — a continuing process to reduce cost and leverage opportunities in order to be prepared to meet emerging challenges.

Values are the principles, standards, and qualities the CBDP organization follows to accomplish the mission, achieve the goals and attain the vision. They direct the size, focus, and coordination of the program—not program outcomes. The values provide statements that identify both the ways and means of the program and also consequences of the program that may result from the successful accomplishment of program goals and missions.

- ***Deter the use of chemical and biological warfare agents***.
  – Deny the advantage of the potential effective use of chemical or biological warfare agents by an initiator through a system of capabilities to avoid, protect against, and sustain operations in a contaminated environment —with only minimal performance degradation from either the effects of the agents or any protective equipment or medical countermeasures.
- ***Ensure all capabilities provided respond to validated threats.***
  – Provide capabilities that address the highest priority CB agent threats, from immediate and validated threats through potential far term or emerging threats. Intelligence efforts must emphasize preparation of tailored intelligence documents that identify and assess threats from the full spectrum of potential chemical and biological warfare agents, and include collection and analysis of nations' "dual-use" chemical and biological industrial capabilities and the indications and warning of adversarial use of dual-use capabilities. Tailored intelligence documents are essential for assessing, developing and updating requirements for CB defense programs.
- ***Provide capabilities to ensure that the warfighter can survive in a chemical or biological environment and complete all operational and support missions***.
  – Provide capabilities that support the prioritized needs of the warfighter and requirements outlined in the Defense Planning Guidance and National Military Strategy.
- ***Maintain technological advantage over any potential adversaries and prevent technological surprise.***
  – Evaluate and leverage continuous improvements in the state-of-the-art in sciences and technologies.
- ***Emphasize a Joint Service approach to chemical and biological defense research, development, and acquisition.***
  – Eliminate unnecessary redundancies among the Services and Defense Agencies, leverage common technologies and requirements, and provide capabilities for Service-unique missions. Ensure coordination among U.S. government agencies and among U.S. allies to field the best available chemical and biological defense capabilities.

- ***Participate in international cooperative and collaborative efforts to leverage technology development and to achieve commonality, interoperability, and systems integration among U.S. allies and coalition partners.***
- ***Provide the most up-to-date doctrine and tactics, techniques, and procedures to solve deficiencies and for the employment of newly developed materiel.***
  – Provide guidance to the warfighter on proper operating procedures utilized in a chemical and/or biological environment.
- ***Provide the best training opportunities to ensure the readiness of the Force to fight in an asymmetric environment.***
  – Ensure that the development of new equipment includes embedded simulation and training capabilities.
- ***Complete critical RDT&E and acquisition of improved chemical and biological detection, identification and warning systems, individual and collective protection systems, medical support and decontamination systems.***
  - Ensure that the warfighter's needs are met in a timely fashion by improving the capabilities of existing equipment and technologies.
- ***Provide for a responsive medical modernization strategy to prevent CB casualties or treat them when prevention is impossible so they can return to duty.***
  - Develop effective medical countermeasures to include prophylaxes/pretreatments, diagnostics, therapeutics, and vaccines.

1.3 CBRN Defense Operational Goals and Supporting Performance Goals

Operational goals are identified by the Services and Combatant Commanders, in coordination with the Joint Staff. **Figure 4**, on the following page, defines the key operational goals related to CBRN defense. The operational goals directly support Corporate Goals 1 and 2. Operational goals support the mission areas of passive defense, force protection, and consequence management. For each of these mission areas, there are functional capabilities to sense, shape, shield, and sustain in response to and in anticipation of CBRN threats. In identifying the operational goals for the missions of passive defense, force protection, and consequence management, the capabilities needed to support these goals are similar. The reference numbers of the operational goals shown in Figure 4 highlight area of close correspondence among goals in the related mission areas. Where unique operational capabilities are needed for the difference missions, separate performance goals are highlighted in the tables following this figure.

Figure 4. CBRN Defense Operational Goals

	Sense (Reconnaissance, Detect and Identify)	Shape (Battle Management)	Shield (Individual & Collective Protection)	Sustain (Decon & Restore)
Passive Defense	1. **Dominate the Battlespace through Reconnaissance, Surveillance, and Target Acquisition** *(Early Warning and NBC Reconnaissance)* 2. **Enhance the Situational Awareness of Unit Battlespaces** *(Automatic Point Detection and Medical Surveillance)*	3. **Provide Hazard Information to Influence Current Operations** *(Battle Mgmt Systems, Battle Mgmt Analysis, Modeling & Simulation)*	4. **Enhance Personnel Survivability Against CBRN Hazards** *(Ind. CBRN Monitors, Prot. Ensembles, Medical Prophylaxes, Individual Decon)* 5. **Maintain Ground, Air, and Maritime OpTempo Through Materiel Enhancements** *(Mobile/Transportable Collective Protection, Operational Decon, NBC Contamination Survivability)*	6. **Sustain Operations, Recovery and Restoration Efforts** *(Fixed Site Collective Protection, Thorough Decontamination, Medical Diagnosis & Treatment, Logistics, Readiness and Training)*
Force Protection	1. **Maintain Situational Awareness of CBRN Hazards outside the Protected Area** *(Early Warning and NBC Reconnaissance)* 2. **Maintain Situational Awareness of CBRN Hazards within the Protected Area** *(Automatic Point Detection and Medical Surveillance)*	3. **Provide Hazard Information to Warn Threatened Personnel** *(Hazard Prediction, Mass Alert Capability, Integration with Civil Information Systems)*	4. **Ensure Protection of All Personnel on an Installation** *(Protective Ensembles, Medical Prophylaxes, Medical Diagnosis & Treatment, Personal/Patient Decon)* 5. **Initiate Recovery/ Reconstitution Operations to Maintain Critical Installation Operations** *(Mobile/Transportable and Fixed Site Collective Protection, Operational Decon, Installation Emergency Response)*	*(Provided through Consequence Management forces)*
Consequence Management	1. **Survey and Monitor the Extent of Hazard Areas** *(Early Warning and NBC Reconnaissance)* 2. **Identify Unknown Hazards to Safeguard Civilians and Responders** *(Automatic Point Detection and Medical Epidemiology)*	3. **Provide Hazard Information to Guide Decision-Makers** *(Hazard Prediction, Integration with Civil Information Systems)*	4. **Ensure Protection of Emergency Responders** *(Individual (manual) Detection, Protective Ensembles, Medical Prophylaxes, Individual Decontamination)* 5. **Maintain Essential Public Services** *(Mobile/Transportable Collective Protection, Operational Decon)*	6. **Restore and Protect Civil Infrastructure** *(Support to State/Local Emergency Response, Thorough Decontamination, Logistics)*

This section identifies each Operational Goal and supporting performance goals. Operational Goals are key operational objectives of the warfighters, which are identified as Combatant Command Requirements in *The Joint Service NBC Defense RDA Plan*. Performance goals are key objectives or capabilities that, if achieved, will support attainment of the Operational Goals. Performance goals are not specific projects or programs. Because the CBDP is established to coordinate and integrate RDA programs for chemical and biological defense within the Department, the key performance measures for the performance goals are specific projects and programs, including the cost and schedule of key programs, as well as the performance of the

systems in achieving the objective and required performance parameters as defined in requirements documents and the number of systems fielded. Based on the specific system identified, there are some projects and systems that may support multiple performance goals or operational goals. These performance measures are similar to performance measures used in other DoD GPRA performance plans.

Additional performance measures include non-material solutions for achieving goals. Non-material solutions include, among other things, training, doctrine, and sustained logistics capabilities. These additional efforts may be included as performance measures in future performance plans. Information and specific data on these efforts may be found in the Annual CBDP Report in Chapter 3 (Logistics) and Chapter 4 (Doctrine, Training, and Readiness). For purposes of this initial performance plan, performance measures focus on the core effort of the CBDP—that is, RDA programs and systems. The success of the CBDP is measured based on the ability to provide systems and capabilities to the U.S. forces so that they may achieve their operational objectives in a contaminated environment. For each performance goal the current materiel solution and the projected future materiel solution is listed. These systems are assessed for progress towards meeting targets. In some cases, current materiel solutions are legacy systems, which means that all planned procurement is complete and these systems will not have any procurement targets to assess.

The following tables provide a summary of all Operational Goals and their supporting performance goals. (Note: the goal numbers are provided for reference purpose and may not indicate priority.) The operational goals for the missions of passive defense, force protection, and consequence management are listed in Figure 4 above. While only the wording for passive defense operational goals is listed below, there is not an omission of capabilities. In operational practice, passive defense, force protection, and consequence management represent different phases of response using similar if not identical capabilities. Where there are unique aspects of these missions, the supporting performance goals highlight these differences.

Operational Goal 1

- **Dominate the Battlespace through Recon, Surveillance, and Target Acquisition (*Passive Defense)***
- **Maintain Situational Awareness of CBRN Hazards outside the Protected Area (*Force Protection*)**
- **Survey and Monitor the Extent of Hazard Areas (*Consequence Management*)**

Supporting Performance Goals:

1.1 Detect, identify, and range all CW at a distance agents to provide early warning of hazards.
1.2 Detect and identify all BW agents at a distance to provide early warning of hazards.
1.3 Recon battlespace for potential NBC contamination hazards in a deployable and survivable military vehicle.
1.4 Maintain surveillance of potential BW agent presence at fixed sites within the theater of operations.

Operational Goal 2

- **Enhance the Situational Awareness of Unit Battlespaces (*Passive Defense)***
- **Maintain Situational Awareness of CBRN Hazards within the Protected Area (*Force Protection*)**
- **Identify Unknown Hazards to Safeguard Civilians and Responders (*Consequence Management*)**

Supporting Performance Goals:

2.1 Provide tactical ground units and ships with near-real time BW agent detection and identification capability.
2.2 Provide tactical units and vehicles with automatic CW vapor agent detection and identification capability.
2.3 Provide military units with medical epidemiology capabilities to support civilians and first responders.

Operational Goal 3

- **Provide Hazard Information to Influence Current Operations (*Passive Defense*)**
- **Provide Hazard Information to Warn Threatened Personnel (*Force Protection*)**
- **Provide Hazard Information to Guide Decision-Makers (*Consequence Management*)**

Supporting Performance Goal:

3.1 Enable rapid communication of NBC hazards and data related to NBC defense (specialized forces, operational and logistics planning information) throughout the theater without burdening personnel or resources.

3.2 Provide warning and reporting capability integrated with civilian information systems

Operational Goal 4

- **Enhance Personnel Survivability Against CBRN Hazards (*Passive Defense*)**
- **Ensure Protection of All Personnel on an Installation (*Force Protection*)**
- **Ensure Protection of Emergency Responders (*Consequence Management*)**

Supporting Performance Goals:

4.1 Provide general warfighters with individual protective ensembles that protect against all NBC hazards.
4.2 Provide general warfighters with individual protective masks that protect against all NBC hazards.
4.3 Provide individual chemical detection equipment that allows manual identification of immediate CW hazards.
4.4 Provide aviators with individual protective ensembles that protect against all NBC hazards.
4.5 Provide aviators (fixed and rotary-wing) with individual protective masks that protect against all NBC hazards.
4.6 Provide units with inherent capability to test and adjust protective mask fits for its warfighters.
4.7 Provide warfighters with lightweight protective masks and ensembles for short-term exposure to NBC agents.
4.8 Provide individuals with immediate decontamination capability to reduce life-threatening NBC hazard risk.
4.9 Provide individuals and medics with medical pretreatments for exposure to CW agents.
4.10 Provide individuals and medics with medical post treatments for CW agents.
4.11 Provide individuals and medics with medical pretreatments for BW agents.
4.12 Provide individuals and medics with medical post-treatments for BW agents

Operational Goal 5

- **Maintain Ground, Air, and Maritime OpTempo Through Materiel Enhancements (*Passive Defense*)**
- **Initiate Recovery/ Reconstitution Operations to Maintain Critical Installation Operations (*Force Protection*)**
- **Maintain Essential Public Services (*Consequence Management*)**

Supporting Performance Goal:

5.1 Provide crewmembers with a limited capability to reduce the level of contamination on vehicles and weapon systems.
5.2 Provide an operational capability to reduce the level of contamination on vehicles and weapon systems.
5.3 Ensure vehicles, vans and ships have a protected environment that keeps NBC hazards out.
5.4 Provide a hazard-free environment for mobile command and control operations.

Operational Goal 6

- **Sustain Operations, Recovery and Restoration Efforts (*Passive Defense*)**
- **Restore and Protect Civil Infrastructure (*Consequence Management*)**

Supporting Performance Goals:

6.1 Provide units with a capability to eliminate all contamination on vehicles and weapon systems.
6.2 Provide units with a capability to eliminate all contamination on terrain and fixed sites.
6.3 Provide units with a capability to eliminate all contamination on sensitive equipment and avionics.
6.4 Provide units with a capability to eliminate all contamination on vehicle/aircraft interiors.
6.5 Monitor the presence/absence of CW agent contamination after decon.
6.6 Monitor the presence/absence of CW agent contamination in water.
6.7 Provide a hazard-free environment for long-term command and control operations.
6.8 Provide a hazard-free environment for forward tactical medical operations.
6.9 Provide a hazard-free environment for long-term rear-area medical operations.
6.10 Develop medical identification and diagnosis device capable of identifying multiple BW agents in clinical and environmental sources.
6.11 Provide support to state and local emergency response teams.

1.4 PERFORMANCE PLAN METHODOLOGY

1.4.1 Data Analysis

In order to measure the performance of individual programs within the overall CBDP, programs are assessed to determine how each actually performed in comparison to the stated program targets. The specific targets represent the program objectives for each year. **Figure 5** illustrates the sources of information that allow a comparison over time. As illustrated, the *targets* for each fiscal year (FY) are derived for that year's corresponding President's Budget Submission to Congress. The accomplishments are reported in the President's Budget Submission immediately following the completion of that fiscal year. Thus, the FY04 President's Budget Submission includes FY02 Accomplishments and FY03 and FY04 Targets. In addition, as a consequence of the September 11, 2001 terror attacks and the anthrax contaminated letters of late 2001, funding was added is a separate special appropriation to the FY02 budget after the budget was approved. Thus for some projects, there are accomplishments for FY02 for which there were no targets listed in the FY02 President's Budget Submission.

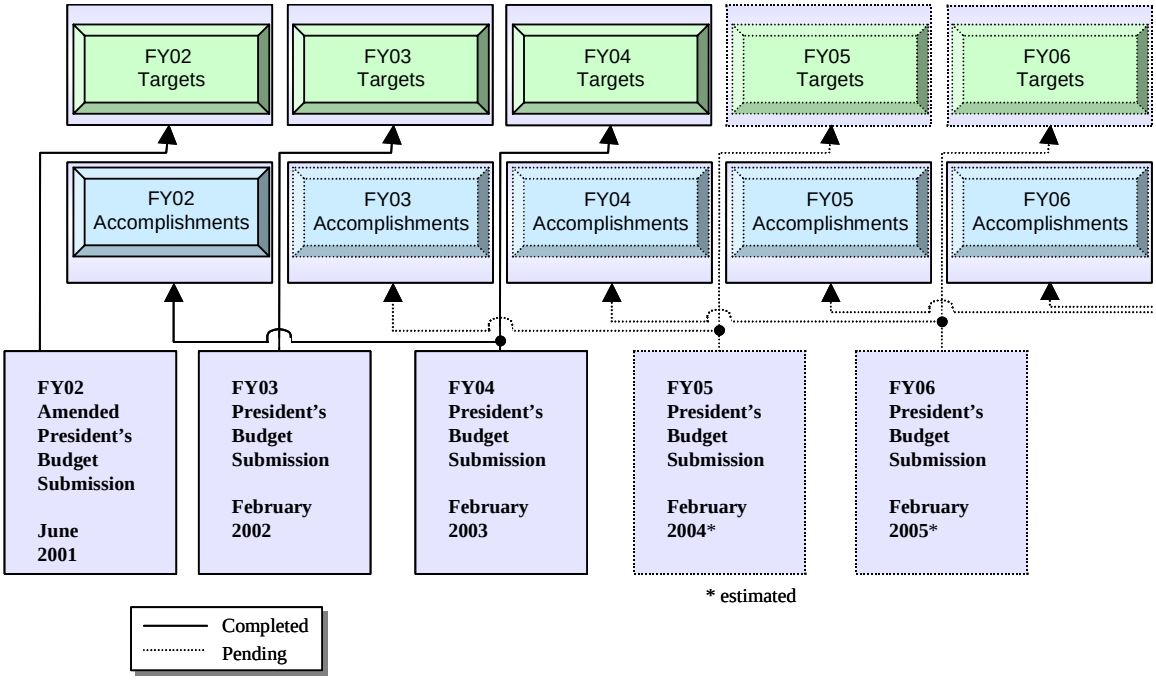

Figure 5. Performance Plan Methodology

This methodology provides a means of ensuring accurate data reporting. Where targets are met, this is stated as "targets met" rather than repeating the targets. Where program accomplishments may be at variance with program targets, the differences are explained. Variances do not necessarily mean poor performance. Variances may occur as a result of schedule changes in supporting programs, changes in funding, or unexpected test results.

When changes are made to a program after the budget is submitted, changes are explained following the completion of that fiscal year. This allows for a fair comparison by providing a detailed description of accomplishments and the variance from the targets. Targets are not changed to reflect accomplishments. Thus, for example, emergency supplemental funds added to the FY02 budget to support efforts to combat terrorism result in changes to the FY02

targets. However, since these changes occurred after the FY02 President's Budget was submitted, the additional resources and targets will be explained in the FY02 accomplishments.

1.4.2 Performance Analysis

Analysis of program data is only part of the assessment process. The next step in the assessment is a comparison of the results of the data analysis against performance goals, operational goals, corporate goals, and the overall CBDP mission.

The CBDP mission is stated in Section 1.2. The CBDP Operational Goals are stated in section 1.3. Operational goals identified by the Services and Combatant Commanders. These goals support the program mission and provide a framework for measuring progress of the various programs under the CBDP in supporting the mission. The operational goals are derived from the *Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan*. In order to provide a link between programs and operational goals, supporting performance goals are developing in coordination with the Joint Staff. Supporting performance goals, detailed in section 1.3, establish a measurable path to incremental achievement of specific operational goals. **Figure 6** illustrates the relationship between the CBDP mission and specific programs.

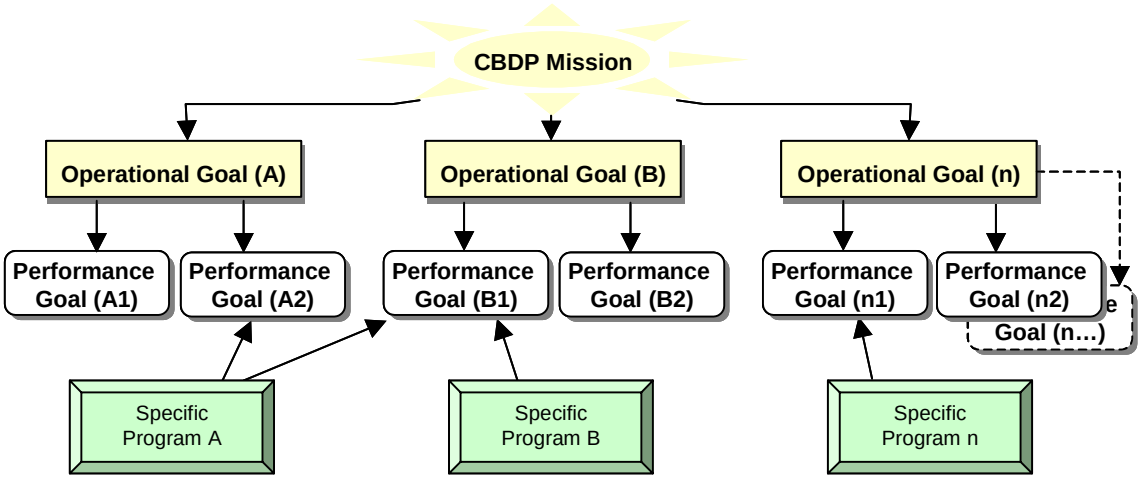

Figure 6. Conceptual Relationship between CBDP Mission and Programs

There are several principles illustrated by this figure:

- Performance goals are driven by and derived from operational goals (which in turn are derived from the program mission.)
- Performance goals are *supported by* programs.
- All funded programs should support a performance goal. (The only exception is for supporting technologies, which are necessary for the development or execution of a program.)
- A program may support more than one performance goal.
- Multiple programs supporting the same performance goal can be evaluated to determine complementarities, synergies, or redundancies.

- Not all performance goals may be supported by a program. This may be the result of the development of a new mission or operational goal, or from the lack of an available technology.
- Programs that do not support a performance goal cannot be demonstrated to support the program mission and may reflect an inappropriate use of resources.

In stating this latter principle, it is important to note that performance measures are *not* operational requirements. Rather, performance measures provide an analytic framework by which programs and operational goals may be linked.

1.4.3 Advanced Development and Acquisition Performance Goals and Measures

The following sections provide near-term performance goals, performance measures, and targets which support program corporate level goals. For the purpose of this strategy plan, FY2002 is the current assessment year, for which actual performance can be assessed; FY2003 and FY2004 are the future assessment years for which targets are established, and will be assessed in future annual performance plans. Future material solutions refer to those that will be addressed during years cited, some of which may be in the technology base.

1.4.3.1 Metric Description. Research, Development and Acquisition (RDA) programs within the DoD CBDP aim to ensure that U.S. forces are provided with the best equipment, which will ensure survivability and mission accomplishment on any future battlefield where chemical or biological agents are employed. The increased complexity of modern warfare demands that CB defense equipment be fielded in the most cost effective and expeditious manner possible. Additionally, the evolving threat environment requires a capabilities-based approach, which requires identifying capabilities that U.S. military forces will need to defend against adversaries since specific adversary's intentions may not be possible to determine. Specific materiel solutions are identified which support numerous Combatant Command requirements. Each materiel solution's progress is measured by monitoring specific performance goals and targets in the planning years. Each of these metrics supports the ultimate objective; that of fielding new and improved CB defense equipment to our warfighting forces.

1.4.3.2 Verification and Validation (V&V) of Metrics. V&V is accomplished through a number of processes. First and foremost, the Planning, Programming, and Budgeting System (PPBS) is the key process employed by the DoD CBDP and is used to ensure that program performance goals and targets are implemented into its budget. Through the PPBS, the program apportions resources annually in support of the goals articulated in the planning process.

The Deputy Assistant to the Secretary of Defense of Chemical/Biological Defense, DATSD(CBD), issues detailed planning guidance annually in the DoD CBDP Program Strategy Guidance, which is used in formulating and preparing the Program Objective Memorandum (POM). This document serves as a strategic planning document, and provides a framework for assessment of the POM and how well it meets stated goals and targets. In conjunction with the publication of the POM, the Joint NBC Board develops an assessment of how well the goals are met. The OSD staff in turn assesses these goals, as the POM is reviewed and adjusted through the summer review process. Preparation of the Budget Estimate Submission (BES) in the fall, begins a new review process, culminating in the finalization of the President's Budget for the DoD CBDP. The PPBS process is an effective mechanism for the DATSD(CBD) to match

Operational CB defense goals and targets with the appropriate budgetary resources in a fiscally constrained environment.

In addition to the annual PPBS process, the DoD CBDP relies on an oversight process, which permits reviews of program status on a monthly basis through staff review of JSCBIS Information Sheets. System PMs and item managers prepare quarterly system summary sheets, which are reviewed by the OSD staff. Selected systems are then selected for review at quarterly In-Process-Reviews held for senior leadership of the DoD CBDP.

Another V&V mechanism used by the CBDP is the Annual Report to Congress. During preparation of the report, the CB defense community reports annual progress within the various facets of the program. Annual accomplishment and plans for the future, as well as issues and factors that limit the ability of the program to achieve its goals, are documented and summarized along with the President's Budget.

ADVANCED DEVELOPMENT AND PROCUREMENT PERFORMANCE GOALS AND MEASURES

2.0 OVERVIEW

Advanced development and procurement within the CBDP is a critical means for ensuring that the U.S. military has the capability to operate effectively and decisively in the face of nuclear, biological, or chemical warfare threats at home or abroad. Advanced development and procurement specifically support **Corporate Goal 1: Develop NBC defense capabilities to meet Joint Acquisition Objectives at reduced costs and on schedule**. The six operational goals outlined in Section 1.3 above provide the link between the programs described below and the overall mission of the CBDP. The following information is provided for each operational goal in this section:

- A list of current and future materiel solutions,
- Procurement data, including:
  (1) an assessment of procurement targets *vs*. actual accomplishments for FY02, and
  (2) procurement targets for FY03 and FY04.
- RDT&E data, including:
  (1) an assessment of RDT&E targets vs. actual accomplishments for FY02, and
  (2) RDT&E targets for FY03 and FY04.
- An overall assessment for activities supporting each operational goal.

2.1 OPERATIONAL GOAL 1: DOMINATE THE BATTLESPACE THROUGH RECON, SURVEILLANCE, AND TARGET ACQUISITION

2.1.1 *Performance Goal 1.1* – Detect, identify, and range all CW agents at a distance to provide early warning of hazards

Current Materiel Solutions	Future Materiel Solutions
M21 Remote Sensing Chemical Agent Alarm (RSCAAL) (Legacy System) AN/KAS-1, Chemical Warfare Directional Detector (Legacy System)	Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD) ARTEMIS, formerly called Joint Service Chemical Warning and Identification LIDAR Detector (JSWILD)

2.1.2 Materiel Solutions Performance Measurements.

2.1.2.1 Current Procurement Targets – JSLSCAD

	FY02		FY03	FY04
Systems	Target	Actual	Target	Target
JSLSCAD	70 [0 of 2,352 procured]	0 (due to rebaselining) [0 of 2,352 procured]	0	121

2.1.2.2 Current Research & Development (R&D) Targets – JSLSCAD

FY 2002 Targets	Actual Performance
- Complete Production Qualification Testing (PQT) and Initial Operation Test & Evaluation (IOT&E). - Complete technical data package and documentation for Milestone C. All program documentation will be reviewed and updated to support MS C. This includes:	- Program rebaselined: MS C changed from FY02 to FY04 due to test scope increases and contract schedule extension. - Completed the integration for the Joint Service Lightweight Nuclear, Biological, Chemical

FY 2002 Targets	Actual Performance
Acquisition Strategy, Acquisition Baseline, Performance Specifications, and Environment Assessment. IPR package preparation and coordination is also included. - Complete review and preparation of technical manuals, logistics support, and training materials. All logistics documentation to include: Technical Manuals; Integrated System Support Plans; and Logistics Support Plans will be updated based on test results. In addition, Materiel Fielding Plans, fielding schedules, and platform integration guides will be prepared and approved.	Reconnaissance System (JSLNBCRS). - Completed the fabrication of 35 PQT/IOT&E Test Articles - Continued PQT/IOT&E Block I which includes environmental extremes, shock and vibration, Electromagnetic Interference (EMI), Electro-magnetic Pulse (EMP), agent and ground vehicle field testing - Continued the preparation and review of technical data package and acquisition documentation

2.1.2.3 Future R&D Targets – JSLSCAD

FY 2003 Targets	FY 2004 Targets
- Continue PQT and IOT&E. - Continue technical data package and acquisition documentation for Milestone C. All program documentation will be reviewed and updated to support MS C. This includes: Acquisition Strategy, Acquisition Baseline, Performance Specifications, and Environment Assessment. IPR package preparation and coordination is also included. - Continue the review and preparation of technical manuals, logistics support, and training materials. All logistics documentation to include: Technical Manuals; Integrated System Support Plans; and Logistics Support Plans will be updated based on test results. In addition, Materiel Fielding Plans, fielding schedules, and platform integration guides will be prepared and approved.	- Complete PQT/IOT&E. - Complete Technical Data Package and acquisition documentation for MS C. Prepare and coordinate In Process Review (IPR) package. Conduct MS C IPR.

2.1.2.4 Current R&D Targets –Artemis

FY 2002 Targets	Actual Performance
- Complete performance specification and update Acquisition Program Baseline and C^4ISR Support Plan. Prepare source documentation for MS B. Maintain document library and information network for all data, research, and other program information. Finalize and issue RFP, conduct source selection for prototype development contractor, conduct review of draft system work breakdown structure, preliminary functional baseline, and draft systems specification. - Finalize Systems Architecture and Systems Specification through a Joint Systems Engineering IPT. Analyze the ORD and develop performance specifications for prototype development. Conduct risk analyses. - Update Simulation Based Acquisition Strategy and Simulation Support Plan to identify the effective use of modeling and simulation throughout the system life cycle. Update/validate the virtual prototype model to support design of early prototype system. Update cost model to reflect new system architecture. Evaluate infrared spectra scene generator equipment in support of virtual testing.	- ARTEMIS - Prepared draft source documentation for Milestone (MS) B. Maintained document library and information network for all data, research, and other program information. Performed financial management, scheduling, planning, and reporting. - Initiated the development of the systems architecture and draft systems specification through a Joint Systems Engineering (SE) Integrated Product Team (IPT). Initiated initial risk analyses and developed initial risk mitigation plan. - Conducted, as an integral part of the systems engineering process, a supportability analysis. Conducted initial Joint Training Planning Process Methodology (TRPPM) and initiated development of an initial Joint System Training Plan (JSTRAP). Began the development of an acquisition logistics support plan for MS B. - Established draft test strategy and began the development of a test methodology. Began the development of an initial Test & Evaluation Master Plan (TEMP) through a Joint Test & Evaluation (T&E) IPT.

FY 2002 Targets	Actual Performance
- Conduct a supportability analysis. Conduct initial Joint Training Planning Process Methodology and develop initial Joint System Training Plan. Develop acquisition logistics support plan for Milestone B through a Joint Logistics/Product Support IPT. - Develop test methodology in support of the test strategy and finalize initial Test & Evaluation Master Plan for Milestone B through a Joint Test & Evaluation IPT. - Further develop components of LIDAR system for a systems architecture and to reduce overall risk by utilizing Advance Component Development. Perform testing on high-risk components to validate performance.	- Continued the development of key components of an active emitter multi-wave Light Detecting and Ranging (LIDAR) technology to develop a system architecture and to reduce overall programmatic risk. Key components considered high risk are solid state lasers, non-consumable detectors, and advanced detection algorithms. Began the advanced component development and prototypes of the performance of these components. - Supported the SE IPT through Simulation Based Acquisition (SBA) activities to reduce cost, schedule, and performance risks; increase the quality, military worth, and supportability of fielded systems; and reduce total ownership costs throughout the system life cycle.

2.1.2.5 Future R&D Targets –Artemis

FY 2003 Targets	FY 2004 Targets
- ARTEMIS - Continue to prepare source documentation for MS B and issue draft Request for Proposal (RFP). Maintain document library and information network for all data, research, and other program information. Perform financial management, scheduling, planning, and reporting. Continue SBA activities to reduce cost, schedule, and performance risks; increase the quality, military worth, and supportability of fielded systems; and reduce total ownership costs throughout the system life cycle. Continue to develop and update the JSTRAP and the supportability analysis. - Continue to develop system architecture, draft system specification, conduct risk analyses and develop risk mitigation plan through a Joint SE IPT. - Continue test strategy and test methodology development to include simulant to real agent correlation and agent fate. Continue TEMP development through a Joint T&E IPT. - Continue risk reduction efforts to further reduce overall program risk in support of the development of key components of an active emitter multi-wave LIDAR technology. Key components considered high risk are solid state lasers, non-consumable detectors, and advanced detection algorithms. Demonstrate and validate performance of these components. - Support the development of standoff detection test infrastructure to provide the capability to adequately test the Artemis system. Develop an active standoff chamber fixture for testing the Artemis system against live chemical warfare agents. Develop precise referee systems to support evaluation of the Artemis system in an open air simulant test.	- ARTEMIS - Update MS B program documentation, conduct MS B decision, and issue final RFP. Maintain document library and information network for all data, research, and other program information. Perform financial management, scheduling, planning, and reporting. Continue SBA activities to reduce cost, schedule, and performance risks; increase the quality, military worth, and supportability of fielded systems; and reduce total ownership costs throughout the system life cycle. Continue to develop and update the JSTRAP and the supportability analysis. - Finalize system architecture, system specification and risk mitigation plan through a Joint SE IPT. - Continue test strategy and test methodology development to include simulant to real agent correlation and agent fate. Finalize TEMP through a Joint T&E IPT

2.1.3 *Performance Goal 1.2* – Detect and identify BW agents at a distance to provide early warning of hazards

Current Materiel Solutions	Future Materiel Solutions
n/a	Joint Biological Standoff Detection System (JBSDS)

2.1.4 Materiel Solutions Performance Measurements

2.1.4.1 Current Procurement Targets

No procurement for standoff biological agent detection systems is planned during FY2002–04.

2.1.4.2 Current R&D Targets – JBSDS

FY 2002 Targets	Actual Performance
- Complete system development and integration of the lightweight, early warning JBSDS system. - Initiate testing of the integrated, lightweight early warning system.	- FY 02 targets not met. - Continued system development and integration of a lightweight, short range, biological standoff detection system. - Two contractors built candidates for testing. One contractor built two systems at $750K each, and the other, three systems at $500K each.

2.1.4.3 Future R&D Targets – JBSDS

FY 2003 Targets	FY 2004 Targets
- Initiate the transition of the early warning standoff systems developed in the TT-Bio program into the Systems Integration phase of the JBSDS program. This includes software development, modeling and simulation analysis, and preparation of program documentation. - Initiate and complete Developmental Testing (DT) of competing candidate systems.	- Initiate Initial Operational Test and Evaluation. - Initiate Development Testing (Production Verification Test) of the Low Rate Initial Production (LRIP) units. - Initiate development of next generation JBSDS system. This includes modeling and simulation analysis, and market research analysis. - Select one of two competing candidate systems and award a development contract. Initiate Low Rate Initial Production (six systems at $800K each).

2.1.5 *Performance Goal 1.3* – Recon battlespace for potential NBC contamination hazards in a deployable and survivable military vehicle

Current Materiel Solutions	Future Materiel Solutions
M93A1 NBC Recon System (Block I) Biological Integrated Detection System	M93A1 NBC Recon System (Block II) Joint Light NBC Recon System (HMMWV/LAV)

2.1.6 Materiel Solutions Performance Measurements

2.1.6.1 Current Procurement Targets – NBCRS (Block II)

	FY02		FY03	FY04
Systems	Target	Actual	Target	Target
M93A1 NBC Recon System (Block II) Renamed NBCRV	0 0 of 95 procured	0 0 of 95 procured	0	17

2.1.6.2 Current R&D Targets – NBC Reconnaissance Vehicle (NBCRV)

FY 2002 Targets	Actual Performance
- Conduct Modeling and Simulation (M&S) of human factors. - Continue sensor suite engineering development and acquisition of detectors. - Continue integration of developmental detectors into vehicles. - Initiated warfighter operational capability assessments.	- All targets met.

2.1.6.3 Future R&D Targets – NBCRV

FY 2003 Targets	FY 2004 Targets
- Complete NBCRS sensor suite engineering development and conduct Interim Progress Review to begin Low Rate Initial Production phase. - Complete Production Qualification Test (PQT) & Early User Test.	- n/a (Product transition to procurement.)

2.1.6.4 Current R&D Targets – Joint Lightweight NBC Reconnaissance System, HMMWV/LAV variants (JSLNBCRS)

FY 2002 Targets	Actual Performance
- Start IOT&E. - Continue LUT of HMMWV variant at the US Army Test Activity. - Start software and hardware engineering development and integration of commercial off the shelf, government off the shelf software, hardware, and non-developmental item software hardware products to the maximum extent possible for HMMWV & LAV variants. - Continue Developmental Test II at Dugway and Yuma Proving Grounds. - Initiate TIC and TIM software development for CBMS transition to JSLNBCRS procurement.	- Completed software and hardware engineering development and integration of commercial off the shelf, government off the shelf software/hardware, and non-developmental item software/hardware products for HMMWV variant. - Conducted system test and evaluation (HMMWV DTII/Limited User Team) at Dugway and Yuma Proving Grounds. - Initiated LAV variant design/fabrication. - Complete procurement, and contractor logistics support services for residual support on Operational Manager selected technologies.

2.1.6.5 Future R&D Targets – JSLNBCRS

FY 2003 Targets	FY 2004 Targets
- Start DT I for LAV variant. - Continue development of TICs and TIMs software for CBMS Block II transition to JSLNBCRS procurement. - Conduct DT III for LRIP HMMWV variants. - Start IOT&E for LAVs and HMMWVs for full rate production/Milestone C.	- Complete IOT&E for HMMWV/LAV variants. - Prepare MS C Full Rate Production documentation; technical data package, ILS spares and provisioning, and fielding preparation. - Continue Toxic Industrial Chemicals (TICs) and Toxic Industrial Materials (TIMs) software development for CBMS Block II transition to JSLNBCRS procurement. Initiate improvements to biological detection/identification capability.

2.1.7 *Performance Goal 1.4* – Maintain surveillance of potential BW agent presence at fixed sites within the theater of operations.

Current Materiel Solutions	Future Materiel Solutions
Portal Shield Biological Integrated Detection System (BIDS)	Joint Biological Point Detection System (JBPDS)—Block I, and II

2.1.8 Materiel Solutions Performance Measurements

2.1.8.1 Current Procurement Targets – JBPDS

	FY02		FY03	FY04
Systems	Target	Actual	Target	Target
Joint Biological Point Detection System	16 [16 of 2,793 procured]	23 [23 of 2,793 procured]	133	170

2.1.8.2 Current R&D Targets – JBPDS

FY 2002 Targets	Actual Performance
Block I Program: Initiate IOT&E (Army at Dugway Proving Grounds).	- Initiated Army IOT&E and began reporting - Achieved a 10-fold increase in laser life over EMD. Reduced false detections with improved algorithm
Block II Program: - Initiate software development and documentation. Develop advanced algorithms that will enhance the JBPDS Block II ability to discriminate background environment aerosol components, while not sacrificing its sensitivity and responsiveness to biological warfare attacks. - Initiate early integrated logistics support to ensure the lowest possible life cycle costs and supportablility of the Block II system in the field. - Initiate component selection, fabrication, and evaluation to develop and refine the critical components of the Block II that will give the system the performance capabilities required in the JORD. - Initiate system level hardware development, integration, evaluation, and documentation to ensure that individual components can be successfully integrated into a functioning, coordinated system to meet system automation, and ensure component compatibility. - Support a joint field trial conducted to identify technologies - Support the hardware selection, fabrication, and evaluation efforts necessary to develop and refine the critical components that will ensure the JBPDS Block II system meets the performance capabilities required by the JORD.	Targets not met. - Targets not met due to inadequate funding *Justification*: - Block II JBPDS Program funds removed

2.1.8.3 Future R&D Targets – JBPDS (Block I Program)

FY 2003 Targets	FY 2004 Targets
- Complete US Army IOT&E (Army at Dugway Proving Ground, UT) and final report. - Initiate USMC IOT&E (Eglin Air Force Base, FL). - Initiate US Air Force IOT&E (Eglin Air Force Base, FL).	- Complete and transition Advanced Biological Aerosol Warning System (BAWS) upgrade to Low Rate Initial Production (LRIP) to meet Joint Operational Requirements Documents (JORD) objective requirements for detection. Initiate identifier upgrade. Incorporate software upgrades featuring prognostics for enhanced maintenance and reliability. - Initiate configuration management including Reliability, Availability, and Maintainability, and Integrated Logistics Support (ILS). - Complete and report USAF, USMC, and USN of IOT&E.

2.2 OPERATIONAL GOAL 2: ENHANCE THE SITUATIONAL AWARENESS OF UNIT BATTLESPACES

2.2.1 *Performance Goal 2.1* – Provide tactical ground units and ships with near-real time BW agent detection and identification capability.

Current Materiel Solutions	Future Materiel Solutions
None	Joint Biological Point Detection System (JBPDS)

2.2.2 Materiel Solutions Performance Measurements – JBPDS (see §2.1.4.2)

2.2.3 *Performance Goal 2.2* – Provide tactical units and vehicles with automatic CW vapor agent detection and identification capability.

Current Materiel Solutions	Future Materiel Solutions
M8A1 Chemical Agent Alarm (Legacy) M22 ACADA Improved (CA) Point Detection System (IPDS)	Joint Chemical Agent Detector (JCAD)

2.2.4 Materiel Solutions Performance Measurements

2.2.4.1 Current Procurement Targets – JCAD

	FY02		FY03	FY04
Systems	Target	Actual	Target	Target
Joint Chemical Agent Detector (JCAD)	0 [0 of 216,126 procured]	0 [0 of 216,126 procured]	773	395

2.2.4.2 Current R&D Targets – JCAD

FY 2002 Targets	Actual Performance
- Complete hardware and software for production representative units delivery and reports. - Complete system development and demonstration for final production representative units. - Complete system integration on final MS III representative units. - Complete Phase II engineering test and evaluation, production qualification tests, and operational tests.	- Continued hardware and software development on 234 contractor prototype units at an average unit cost of $7272. - Continued systems engineering and logistics planning. - Began system interface design of JCAD system components and user platforms. - Completed contractor validation test and evaluation. Began government development tests (DT) on 234 prototype units at an average system unit cost of $7272. Continued to plan for government operational testing.

2.2.4.3 Future R&D Targets – JCAD

FY 2003 Targets	FY 2004 Targets
- Complete hardware and software development based upon results from contractor and government developmental testing. - Continue systems engineering and logistics planning. Begin engineering support for LRIP. - Continue system interface design of JCAD systems and user platforms. - Complete government developmental test and evaluation. - Begin IOT&E using procurement funded LRIP units (790 planned for FY03).	- Complete systems engineering and logistics planning. - Complete government IOT&E using LRIP units, which will be purchased with production funds, at an average unit cost of $7272. - Complete system interface design based on results of government operational tests. - Complete LRIP software update based on results of government operational testing.

2.2.5 *Performance Goal 2.3* – Provide military units with medical epidemiology capabilities to support civilians and first responders.

Epidemiology capabilities include a variety of biological identification systems and decision support tools. Diagnostic systems are critical to epidemiological investigations of disease outbreaks, but are only one part of epidemiological analysis, which also includes analysis of disease frequency, distribution, patterns, risk factors, and other factors that lead to the identification of cause(s) and source(s) of an epidemic and recommendations for countermeasures.

Current Materiel Solutions	Future Materiel Solutions
WMD-Civil Support Team Equipment Critical Reagents Program (CRP)	WMD-Civil Support Team Equipment upgrades CB Installation Force Protection Program (Confirmatory Analysis projects) Joint Medical NBC Decision Support Tool JBAIDS (See section 2.6.20.1)

Note: While the CRP develops and procures reagents for antibody and genetic based detection systems, this program does not provide standalone detection devices, but rather provides critical support to detection and identification systems.

2.2.6 Materiel Solutions Performance Measurements

2.2.6.1 Current Procurement Targets

Systems	FY02 Target	FY02 Actual	FY03 Target	FY04 Target
Analytic Laboratory System (ALS)*	36 [36 of 36 procured]	36 [36 vehicles procured]	0	0
Ruggedized Advanced Pathogen Identification Device (RAPID)**	0 [0 of 0 procured]	0 [0of 0 procured]	18	0

* Procured in support of the WMD Civil Support Teams
** Procured as part of the CB Installation Force Protection Programs

2.2.6.2 Current R&D Targets – ALS Upgrade

FY 2002 Targets	Actual Performance
- n/a (new start in 2003)	- n/a (New start).

2.2.6.3 Future R&D Targets

FY 2003 Targets	FY 2004 Targets
- Initiate development of Analytical Laboratory System (ALS) upgrades. - Initiate support and planning ALS upgrade program.	- Continue development of ALS upgrades.

2.3 OPERATIONAL GOAL 3: PROVIDE REAL-TIME HAZARD INFORMATION TO INFLUENCE CURRENT OPERATIONS

2.3.1 *Performance Goal 3.1* – Enable rapid communication of NBC hazards and data related to NBC defense (specialized forces, operational and logistics planning information) throughout the theater without burdening personnel or resources.

Current Materiel Solutions	Future Materiel Solutions
Joint Warning and Reporting Network (JWARN) Block I (Interim Standardization)	JWARN Block II JWARN Block III Joint Effects Model (JEM)

2.3.2 Materiel Solutions Performance Measurements

2.3.2.1 Current Procurement Targets – JWARN Block I

Systems	FY02		FY03	FY04
	Target	Actual	Target	Target
Joint Warning and Reporting Network (JWARN) Block I	0 [0 of 3,158 procured]	0 *(See note)	0	2,472

* **Note**: Block I fielding was completed. It was a software integration effort based on urgent need requirements identified by the U.S. Marine Corps and the U.S. Army. Block I standardized NBC warning and reporting throughout the services. During the Block I effort, the joint services procured Commercial-Off-The-Shelf (COTS) NBC warning and reporting software and three Government-Off-The-Shelf (GOTS) downwind hazard prediction models. COTS software was bundled with GOTS software and distributed to all services. The objective of Block I was first to meet an urgent need identified by the U.S. Army and the U.S. Marine Corps for automated NBC warning and reporting tools, and second to standardize NBC Warning and Reporting requirements across the Services.

2.3.2.2 Current R&D Targets – JWARN – Block II and III

FY 2002 Targets	Actual Performance
- Continue Block II integration of NBC legacy and future detector systems. - Develop NBC warning and reporting modules and battlespace management modules for use by Joint Services C4I systems. - Conduct Block II modeling and simulation - Conduct Block II system T&E. - Prepare integrated logistics support technical data.	- Started Block II integration of NBC legacy and future detector systems. Initiated development of NBC warning and reporting modules and battlespace management modules for use by Joint Services C4I2 systems. - Started Block II Modeling and Simulation for compatibility with the Joint Effect Model (JEM). - Prepared Block II system DT II for Key Performance Parameters/Operational Assessment. - Prepared integrated logistics support technical data and Test and Evaluation Master Plan (TEMP).

2.3.2.3 Future R&D Targets – JWARN – Block II and III

FY 2003 Targets	FY 2004 Targets
- Continue Block II integration of NBC legacy and future detector systems and conduct Development Testing (DT) and Operational Assessment (OA) for full system requirements. - Prepare documentation for Block II MS C.	- Continue Block II integration of GCCS level C4ISR systems and interface development. - Conduct DT/OA. - Prepare documentation for Block III Milestone C.

2.3.2.4 Current R&D Targets – Joint Effects Model (JEM) Block I

FY 2002 Targets	Actual Performance
- *FY 2003 New Start*	- *FY 2003 New Start*

2.3.2.5 Future R&D Targets – JEM Block I and II

FY 2003 Targets	FY 2004 Targets
- Complete transition from tech base. Integrate counterforce, passive defense, and hazard/incident software models into a complete system. Develop logistics documentation, initiate Post Deployment Software Support planning, and establish online document library and information network for all data, research, and other program information. Update MS B program documentation and conduct MS B decision. Conduct source selection for development of a standardized hazard prediction model. Perform financial management, scheduling, planning, and reporting.	- JEM Block I - Complete development of logistics/ training plans and materials. Complete Post Deployment Software Support (PDSS) plans. Conduct MS C. Support continued Warfighter Integrated Process Team (IPT) involvement in program. Perform financial management, scheduling, planning, and reporting. - JEM Block I - Award contract for formal software development. Finalize service command and control system integration plans. Complete formal software development. Perform contractor level software testing. Perform integration activities with all service

FY 2003 Targets	FY 2004 Targets
- Develop TEMP and Verification, Validation, and Accreditation (VV&A) plan. Complete analysis of existing field test data associated with the hazard prediction models Vapor, Liquid and Solid Tracking (VLSTRACK), Hazard Prediction and Assessment Capability (HPAC), and Personal Computing Program for the Chemical Hazard Prediction (D2PC) and identify data gaps. Prepare for and conduct Early Operational Assessment (EOA). Initiate Independent Validation and Verification (IV&V) effort. Develop and refine warfighter use cases. Perform engineering analysis and evaluation of software design documentation. Establish and conduct Configuration Control Board (CCB). Continue technical data transition of HPAC, VLSTRACK, and D2PC models. - Award contract for the development of engineering builds (software only) in support of the Block I for transition to the SDD phase.	Global Command and Control System (GCCS) variants and other Command and Control (C2) system. Verify system interoperability requirements - JEM Block I - Conduct Developmental and Operational testing. Continue Independent Validation & Verification (IV&V). Update the Test and Evaluation Master Plan (TEMP) and the Verification Validation and Accreditation (VV&A) plan to support Milestone (MS) C. Produce T&E and VV&A reports.

2.3.3 *Performance Goal 3.2* – Provide warning and reporting capability integrated with civilian information systems.

See Section 2.3.1 above (JWARN Block II)

2.4 OPERATIONAL GOAL 4: ENHANCE PERSONNEL AND EQUIPMENT SURVIVABILITY

2.4.1 *Performance Goal 4.1* – Provide general warfighters with individual protective ensembles that protect against all NBC hazards.

Current Materiel Solutions	Future Materiel Solutions
Battledress Overgarment (Legacy System) Saratoga, JS Lightweight Integrated Suit Technology (JSLIST) Black Vinyl Overboots (Service O&M responsibility) 7, 14, 25-mil Gloves (Service O&M responsibility)	JSLIST Block I and II Glove Upgrades

2.4.2 Materiel Solutions Performance Measurements

2.4.2.1 Current Procurement Targets – JSLIST

	FY02		FY03	FY04
Systems	Target	Actual	Target	Target
JSLIST	361,024 [1,921,106 of 6,848,136 procured]	388,154 [1,948,236 of 6,848,136 procured]	334,205	271,183

2.4.2.2 Current R&D Targets – JSLIST Block I Glove Upgrade

FY 2002 Targets	Actual Performance
- Initiate engineering and design of an integrated JSLIST Block II glove for DT/OT to meet air/ground usage requirements in a CB environment. - Prepare program documentation of MS C.	– FY 02 Targets met. – Completed requirements analysis of JBIGU program results for transition to JBIIGU programs. Formed JBIIGU program team, conducted market survey and completed Acquisition Strategy.

2.4.2.3 Future R&D Targets – JSLIST Block II Glove Upgrade

FY 2003 Targets	FY 2004 Targets
- Award multiple competitive contracts for system development and demonstration. - Conduct durability and chemical validation testing for air/ground missions. - Conduct project management and plan test readiness reviews. - Conduct air/ground Operational Test (OT) and complete MS C. - Conduct field durability trials for air/ground missions. - Conduct chemical validation test trials. - Conduct air/ground OT and complete Milestone C documentation.	- Complete IOT&E and initiate chemical validation testing. - Conduct preparations for MS C LRIP. - Continue air/ground operational tests and complete MS C. - Form alternative footwear solutions project team, conduct market survey, form Acquisition Strategy, initiate durability and chemical testing.

2.4.3 *Performance Goal 4.2* – Provide general warfighters with individual protective masks that protect against all NBC hazards.

Current Materiel Solutions	Future Materiel Solutions
M40/M40A1 Mask M42 Tank Mask (Legacy) MCU-2A/P Mask (Legacy)	Joint Service General Purpose Mask (JSGPM)

2.4.4 Materiel Solutions Performance Measurements

2.4.4.1 Current Procurement Targets – M40/M40A1 and Second Skin, Mask MCU-2/P

	FY02		FY03	FY04
Systems	Target	Actual	Target	Target
M40/M40A1 Mask	0 [1,341,087 of 786,906 procured]	0 [1,341,087 of 786,906 procured]	*Replaced by JSGPM*	*Replaced by JSGPM*
Second Skin, Mask MCU-2/P	196,812 [196,812 of 615,856 procured]	350,000 [89,667 of 615,856 procured]	1,897,167	0

2.4.4.2 Current R&D Targets – JSGPM

FY 2002 Targets	Actual Performance
- Conduct SDD, which includes system support packages for PQT/IOT&E. The contract includes delivery of 5,000 prototypes ($500 each) in 1QFY04. - Prepare program/project documentation to achieve MS C decision. Documentation includes: Acquisition Strategy, the Manpower and Personnel Integration Plan, and performance specifications. - Execute logistics support plan. - Initiate documentation and planning for DT/OT. - Test redesigned prototype to assess shortcomings exposed during PDRR phase.	- Completed preparation for Interim Progress Review and transition to the System Development and Demonstration acquisition phase. These activities included finalization of the Single Acquisition Management Plan (SAMP), Test and Evaluation Master Plan (TEMP), and the Manpower and Personnel Integration (MANPRINT) Plan. - Completed Program Definition and Risk Reduction contract for mask design and 800 prototypes at $1500 each. Mask was designed to Joint Service performance specifications with Joint Service input. - Conducted and completed Engineering Design Test (EDT). Testing ensured meeting Joint Service requirements for protection, communication, drinking, breathing resistance, and weight/bulk limitations. - Completed sustainment study for logistics support.

2.4.4.3 Future R&D Targets – JSGPM

FY 2003 Targets	FY 2004 Targets
- Continue preparation of program/project documentation to achieve MS C. - Continue execution of logistics support plan. Develop manuals and finalization of supportability plans. - Continue System Demonstration including system support packages for PQT/IOT&E. - Continue documentation and planning for DT/OT. - Continue development of a JSGPM variant as a lightweight complement to the JSGPM against limited threats.	- Continue System Demonstration. System Demonstration includes system support packages for Production Qualification Testing and Initial Operational Testing and Evaluation. - Continue preparation of program/ project documentation. Documentation includes the Manpower and Personnel Integration (MANPRINT) Plan, and Performance Specifications. - Continue Developmental and Operational Testing. Generate test incident reports and corrective action plans to address test results during mask design and production. - Continue preparation of the Logistics Support Plan. This effort includes development of manuals, and finalization of supportability plans. - Continue development of the Joint Service Chemical Environment Survivability Mask (JSCESM) as a lightweight complement to the JSGPM against limited threats. - Initiate development of the Improved Protective Mask (IPM).

2.4.5 *Performance Goal 4.3* – Provide individual chemical detection equipment that allows manual identification of immediate CW hazards.

Current Materiel Solutions	Future Materiel Solutions
M8 paper (Service O&M responsibility) M9 paper (Service O&M responsibility) M256A1 Detector Kit (Service O&M responsibility)	Joint Chemical Agent Detector (JCAD)

2.4.6 Materiel Solutions Performance Measurements: JCAD (see §2.2.4.1 and §2.2.4.2)

2.4.7 *Performance Goal 4.4* – Provide aviators with individual protective ensembles that protect against all NBC hazards.

Current Materiel Solutions	Future Materiel Solutions
Aircrew Uniform Integrated Battledress (AUIB) (Legacy system) Chemical Protective Undercoverall (Service O&M responsibility) CWU-66/77 Aircrew Ensemble (Legacy system)	Joint Protective Aviator Ensemble (JPACE)

2.4.8 Materiel Solutions Performance Measurements

2.4.8.1 Current R&D Targets – JPACE

FY 2002 Targets	Actual Performance
- Complete DT IIA material swatch testing and downselect best six candidate materials. Initiate DT IIB testing on the six candidates to verify system level performance requirements have been met. - Fabricate 75 prototype ensembles of each of the six selected candidates for use in DT IIB. - Complete development of patterns for use in fabrication of JPACE. Continue developing and updating program, logistics, and technical	- Downselected and conducted Milestone B. Awarded two multiyear contracts with Low Rate Initial Production (LRIP) and Full Rate Production (FRP) options to develop two candidate materials based on Developmental Test (DT) IIA material swatch test results. Fabricated 125 prototype ensembles of each of the selected candidates for use in DT IIB (250 total at $525 each). Initiated DT IIB testing on the candidates to verify system

FY 2002 Targets	Actual Performance
documentation required to support the development of JPACE.	level performance requirements have been met. - Completed development of patterns for use in fabrication. Continued developing and updating program, logistics, and technical documentation required to support development and fielding.

2.4.8.2 Future R&D Targets – JPACE

FY 2003 Targets	FY 2004 Targets
- Complete DT IIB testing. Conduct Critical Design Review (CDR). Fabricate 350 prototype ensembles of each candidate for combined DT/Operational Test (OT) (700 total at $525 each). Initiate combined DT/OT system level testing and initial Operational Assessment (OA) to verify system level performance and assess operational suitability and durability. Testing includes aircraft integration testing (crashworthiness, early flight, and aircraft compatibility) on six aircraft and system level chemical simulant testing (Man In Simulant Test). - Continue developing and updating program, logistics, and technical documentation required to ensure that ensembles will be fully supported when fielded. Continue updating garment specifications and patterns.	- Complete combined DT/OT system level testing. Initiate and complete durability testing. Initiate Independent Operational Test & Evaluation (IOT&E) of LRIP ensembles. - Conduct Milestone C decision for LRIP of ensembles. Award contract options to manufacture LRIP ensembles. Fabricate 550 suits from two vendors maximum (1100 total at $525/unit (avg)). Continue developing and updating program, logistics, and technical documentation required to ensure that ensembles will be fully supported when fielded. Initiate finalization of garment specifications and patterns.

2.4.9 *Performance Goal 4.5* – Provide aviators (fixed-wing and rotary wing) with individual protective masks that protect against all NBC hazards.

Current Materiel Solutions	Future Materiel Solutions
Aircrew Eye/Respiratory Protective Mask (AERP)-Legacy System CB Respiratory System M45 Aviation Protective Mask M48 Apache Mask (Legacy System)	Joint Service Aviation Mask (JSAM)

2.4.10 Materiel Solutions Performance Measurements

2.4.10.1 Current Procurement Targets – CB Respiratory System and M48 Mask

	FY02		FY03	FY04
Systems	Target	Actual	Target	Target
CB Respiratory System	666 [5,035 of 7,919 procured]	400 [4,743 of 7,919 procured]	300	0
M48 Protective Mask	0 [0 of 3,877 procured]	4,000 [4,000 of 3,877 procured]	0	0

2.4.10.2 Current R&D Targets – Joint Service Aviation Mask (JSAM) and M48 Mask

FY 2002 Targets	Actual Performance
JSAM - Finalize PDRR test plans/procedures and evaluate PDRR prototypes. The Government will evaluate the prototypes for chemical agent permeation, fit factor, positive pressure breathing at altitude, anti-G endurance, air crew life support equipment integration and aircraft interface checks, human	- FY 02 targets met. - Completed PDRR test plans/procedures. The Government evaluated the prototypes for chemical agent permeation, fit factor, positive pressure breathing for altitude, anti-G endurance (centrifuge), air crew life support equipment

FY 2002 Targets	Actual Performance
factors and environmental factors. - Complete initial development and qualification testing of prototypes. Deliver prototypes to the government for PDRR testing. - Continue system engineering. Support government PDRR prototype testing and prepare for/conduct MS II and transition to system development and demonstration.	integration and aircraft interface checks, human factors and environmental factors. Initiated test planning for system demonstration phase. - Completed contractor qualification test and fabricated prototypes (25 of each variant). Total number of variants and cost per prototype is competition sensitive information. Delivered prototypes to the government for PDRR testing on 30 Jan 2002. - Continued system engineering and program management activities and support government PDRR prototype testing. Prepare for MS B Interim Progress Review (IPR) and transition to System Development and Demonstration. - Conducted System Development and Demonstration (SDD) source selection, MS B Interim Progress Review and awarded SDD contract.
M48 - Award production contracts for bracket and hose assemblies. - Complete M48 system by marrying bracket/hose assemblies to existing M48 parts. - Field M48 systems.	- Successfully transitioned to procurement.

2.4.10.3 Future R&D Targets – Joint Service Aviation Mask (JSAM) and M48 Mask

FY 2003 Targets	FY 2004 Targets
JSAM - Finalize system design and complete development. Begin logistics activities and sustainment planning to include tech order preparation, provisioning, and fielding plan - Continue program management activities, to include updating programmatic and technical documentation. Continue test planning documents such as the Test Evaluation Master Plan in preparation for Developmental Testing (DT) and Operational Testing (OT). - Start and complete system validation, develop production processes and hard tooling to fabricate DT and OT units. - Initiate material buy and begin assembly of DT units.	JSAM - Complete assembly of 500 DT units at an average unit cost of $6112 and continue all contract activities to include logistics/sustainment activities and contractor support of DT. - Conduct of ground DT and flight DT by Government Test and Evaluation agencies on selected aircraft. - Prepare program and technical documentation in preparation for Milestone C. - Continue documentation and planning in preparation for OT and participation of OT agencies during DT

2.4.11 *Performance Goal 4.6* – Provide units with inherent capability to test and adjust protective mask fits for its warfighters.

Current Materiel Solutions	Future Materiel Solutions
M41 Protective Assessment Test System (PATS)	JS Mask Leakage Tester (JSMLT) Miniaturized / Lightweight / Improved PATS

Note: The M41 PATS will be replaced by the JSMLT beginning in FY03.

2.4.12 Materiel Solutions Performance Measurements

2.4.12.1 Current Procurement Targets – M41 PATS

Systems	FY02		FY03	FY04
	Target	Actual	Target	Target
M41 PATS	566 [7,790 of 12,182]	566 [7,790 of 12,182]	1000	0

2.4.12.2 Current Procurement Targets –JSMLT

Systems	FY02		FY03	FY04
	Target	Actual	Target	Target
Joint Service Mask Leakage Tester	*n/a* [0 of 1,439 procured]	*n/a* [0 of 1,439 procured]	1,241	482

2.4.13 *Performance Goal 4.7* Provide warfighters with lightweight protective masks and ensembles for short-term exposure to NBC agents

Current Materiel Solutions	Future Materiel Solutions
None (interim measure-use of M40 series/MCU-2/P) None (interim measure-use of JSLIST)	JS Chemical Environment Survivability Mask (JCESM)

2.4.14 Materiel Solutions Performance Measurements

2.4.14.1 Current R&D Targets – JCESM

FY 2002 Targets	Actual Performance
- JCESM - See Section 2.4.4.2 JSGPM	- See Section 2.4.4.2 JSGPM

2.4.14.2 Future R&D Targets – JCESM

FY 2003 Targets	FY 2004 Targets
- See Section 2.4.4.2 JSGPM	- See Section 2.4.4.2 JSGPM

2.4.15 *Performance Goal 4.8* Provide individuals with immediate decontamination capability to reduce life-threatening NBC hazard risk.

Current Materiel Solutions	Future Materiel Solutions
M291 skin decon kit (Purchase is a Service O&M responsibility) M295 individual equipment decon kit (Purchase is a Service O&M responsibility)	M291 skin decon kit (Sorbent based) M295 individual equipment Decon kit (Sorbent based)

2.4.16 Materiel Solutions Performance Measurements

2.4.16.1 Current R&D Targets – M291 and M295 Decon Kits

FY 2002 Targets	Actual Performance
<u>*M291 Skin Decon Kit (Sorbent)*</u> - Develop end item design using carbon cloth technology to facilitate absorption of the contaminant from the skin - Produce prototype hardware of the M291 skin decon kits with sorbent - Conduct toxicity testing of sorbent for skin decon - Develop engineering change proposal to incorporate sorbent into the M291 skin decon kit <u>*M295 Equipment Decon Kit (Sorbent)*</u> - Develop engineering change proposal for the M295 individual decon kits	*Targets for M291 met with the following exceptions:* - Develop engineering change proposal to incorporate sorbent into the M291 skin decon kit All M295 targets met.

2.4.16.2 Future R&D Targets – M291 and M295 Decon Kits (Sorbent based)

FY 2003 Targets	FY 2004 Targets
- Apply for FDA approval of M291 skin decon kit	- None

2.4.17 *Performance Goal 4.9* Provide individuals and medics with medical pretreatments for exposure to CW agents.

Current Materiel Solutions	Future Materiel Solutions
Soman Nerve Agent Pyridostigmine Pretreatment (SNAPP) (Service O&M responsibility)	Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA) Improved NAPP (Pyridostigmine Bromide) Active Topical Skin Protectant (aTSP) CW Agent Prophylaxis Cyanide Pretreatment

2.4.18 Materiel Solutions Performance Measurements

2.4.18.1 Current R&D Targets – Improved Pyridostigmine Bromide and SERPACWA

FY 2002 Targets	Actual Performance
Pyridostigmine Bromide - Continue storage and stability testing. - Conduct FDA required additional studies.	Pyridostigmine Bromide *FY02 Targets Met* - Continued three studies to validate surrogate markers for human efficacy. (Human ex vivo muscle study, human ex vivo blood study, and higher animal species ex vivo study). - Completed FDA manufacturing study to validate surrogate markers in small animal ex vivo muscle for human efficacy.
SERPACWA - Prepare sample packaging and validate manufacturing procedures for TSP.	SERPACWA - Completed FDA manufacturing requirements, redesigned packaging, continued production line process validation, shelf-life monitoring, and FDA required Phase IV testing.

2.4.18.2 Future R&D Targets – Improved Pyridostigmine Bromide and SERPACWA

FY 2003 Targets	FY 2004 Targets
Pyridostigmine Bromide - Complete storage and stability testing and complete FDA required additional studies. - Finalize and submit NDA to FDA.	Pyridostigmine Bromide - Complete human ex vivo muscle study to demonstrate efficacy vs. surrogate marker.
SERPACWA - Complete FDA manufacturing requirements.	SERPACWA - n/a

2.4.18.3 Current R&D Targets – Active Topical Skin Protectant and CW Agent Prophylaxis

FY 2002 Targets	Actual Performance
- Science and technology base (S&T) program.	- All targets met - See Section 3.6.5.4

2.4.18.4 Future R&D Targets – Active Topical Skin Protectant and CW Agent Prophylaxis

FY 2003 Targets	FY 2004 Targets
- Pending transition from S&T	- Pending transition from S&T

2.4.19 *Performance Goal 4.10* Provide individuals and medics with medical post treatments for CW agents.

Current Materiel Solutions	Future Materiel Solutions
Nerve Agent Antidote Kit (NAAK)* Convulsant Antidote Nerve Agent (CANA) * Sodium thiosulfate/nitrate* Multi-chamber Autoinjector*	Improved CANA Vesicant Agent Countermeasures Advanced Anticonvulsant

*(Service O&M responsibility)

2.4.20 Materiel Solutions Performance Measurements

2.4.20.1 Current R&D Targets – Multi-Chamber Autoinjector and Advanced Anticonvulsant

FY 2002 Targets	Actual Performance
Multi-chamber Autoinjector - Conduct FDA required additional studies for licensure.	- Transitioned to procurement
Advanced Anticonvulsant *Complete multi-year toxicology studies* - Complete 2-year pre-clinical efficacy study in non-human primates. - Formulate advanced anticonvulsant in autoinjector for planned clinical studies.	FY 02 targets met. – Completed 2-year study in surrogate species to validate markers of anticonvulsant efficacy as a model to identify better drugs. – Conducted a bridging study between the current and a different higher animal species model to improve the anticonvulsant animal model. - Completed a literature study to compare midazolam to FDA approved seizure drugs for evidence of respiratory depression - Completed a subject matter expert focus panel to continue the development of midazolam as a replacement for the currently fielded anticonvulsant.

2.4.20.2 Future R&D Targets – Advanced Anticonvulsant

FY 2003 Targets	FY 2004 Targets
- Prepare and submit documentation for Investigational New Drug application. - Continue development of the manufacturing processes, material requirements, formulation, and packaging to be used in clinical studies. - Prepare documentation for a conduct MSII in-process review. - Complete evaluation of FDA approved seizure drugs for nerve agent induced seizures. - Initiate determination of optimum serum levels of midazolam in higher animal species model.	- Initiate and conduct human clinical study to determine maximum tolerated dose of Advanced Anticonvulsant candidates. - Continue optimum serum level studies in higher animal species model study. Continue neuropathological analysis of higher animal species model study.

2.4.21 *Performance Goal 4.11* Provide individuals and medics with pre-treatments for BW agents.

Current Materiel Solutions	Future Materiel Solutions
Anthrax vaccine Smallpox vaccine	Biological Defense Vaccines, *e.g.*, Multivalent Equine Encephalitis, Plague, Ricin and Next Generation Anthrax vaccine

2.4.22 Materiel Solutions Performance Measurements

2.4.22.1 Current R&D Targets – Biological Defense Vaccines

FY 2002 Targets	Actual Performance
- Smallpox Vaccine: Continue consistency lot manufacture and conduct stability testing for Smallpox vaccine. - Initiate Phase 2b clinical trial for Smallpox vaccine. - Initiate neuropathological analysis of non-human primate model study. - Develop manufacturing capability for VIG and initiate BLA process.	- FY 02 targets met. - Smallpox Vaccine - Continued process optimization and completed 3 parts of a smallpox cohort Phase I clinical trial. - Developed manufacturing capability for Vaccinia Immune Globulin (VIG) - Initialized accelerated manufacturing and release of VIG
- Tularemia Vaccine: Continue efficacy testing and begin immunogenicity studies for Tularemia vaccine. - Begin pilot lot manufacturing and stability testing.	- FY 02 targets met. - Completed manufacturing process refinement studies in preparation for production of cGMP pilot lot. - Continued non-clinical and product characterization studies.
- Continue manufacturing process refinement of serotypes for the Recombinant Botulinum Vaccine including antigen and adjuvant characterization and assay development and validation. - Begin pilot lot production of second serotype and conduct non-clinical testing for multivalent Recombinant Botulinum vaccine. - Complete serologies and data analysis of the Pentavalent Botulinum Toxoid booster study and prepare final report for submission to the FDA.	- Most FY 02 targets met. - Completed manufacturing process refinement. - Initiated pilot lot production of individual serotypes and completed production of cGMP lot of serotype B. - FY 02 target not met: Complete serologies and data analysis of the Pentavalent Botulinum Toxoid booster study and prepare final report for submission to the FDA.
- Next Generation Anthrax Vaccine (NGAV): Continue process definition studies including stability and formulation studies.	- FY 02 target met. - NGAV - Conducted process definition studies of candidate recombinant protective antigen NGAV including stability and formulation studies. Submitted IND application for Phase I study. Initiated non-clinical studies.
- Equine Encephalitis Vaccines: Complete process development and initiate safety studies for VEE 1A/B component of the vaccine. - Manufacture cGMP pilot lots for other Multivalent Encephalitis components.	- Equine Encephalitis FY 02 target met: Completed manufacture of cGMP pilot lot and began stability and lot release testing for VEE 1A/B component. - Began assay development and qualification of VEE 1A/B component. - Initiated non-clinical safety studies for VEE 1A/B component. - Initial cross protection studies indicate that V3526 protects against VEE 1E and IIIA therefore, vaccine for VEE could be one component rather than a multivalent.

FY 2002 Targets	Actual Performance
- Plague Vaccine: Continue process development and initiate comparability studies in non-human primates for Plague vaccine. - Initiate assay development and validation.	- Plague vaccine FY 02 targets met. - Initiated assay development and validation. - Continue stability testing and initiate animal testing. - Complete toxicology and immunogenicity testing. - Manufacture cGMP pilot lot and three qualification lots. - Funds preparation and submission of IND application. Conduct Phase I trials, non-human primate studies and perform animal efficacy studies on the UK product in order to collect data for a down-select decision.
- *For Brucella, Plague, VEE vaccines, Staphylococcal Enterotoxin B, see section 3.0: S&T Performance Goals & Measures*	- *n/a*

2.4.22.2 Future R&D Targets – Biological Defense Vaccines

FY 2003 Targets	FY 2004 Targets
Tularemia Vaccine - Complete characterization studies and continue development of surrogate marker of efficacy. - Conduct immunogenicity and toxicity studies. - Complete cGMP pilot lot production and conduct final container stability testing of pilot lot.	- n/a
Recombinant Botulinum Vaccine - Complete adjuvant formulation studies. - Complete bulk cGMP lot production of A/B. - Initiate bulk stability and final container stability testing of pilot lot. - Initiate planning and preparation for Phase I clinical trial. - Complete cGMP pilot lot manufacturing of serotypes A and B bivalent vaccine.	Recombinant Botulinum Vaccine - Initiate process validation, to include qualification and validation of fermentation and purification processes for the manufacture of serotypes A and B. - Submit IND application and initiate Phase I clinical trial execution and monitoring. Conduct non-clinical studies and final container stability testing. - Initiate process development on serotypes C, E and F.
Equine Encephalitis Vaccines - Continue assay development and validation. - Continue stability and lot release testing on cGMP pilot lot of the VEE 1A/B component. - Conduct higher animal species nerovirulence testing and equine safety study of VEE 1A/B component.	Equine Encephalitis Vaccines: - Conduct process development and manufacture of master and working cell banks. - Continue stability testing on cGMP pilot lot of VEE 1A/B component. - Submit IND application. - Conduct Phase I clinical trials on VEE 1A/B component.
Plague Vaccine - Continue process development efforts to include: optimization, formulation, and stability studies, the manufacture of 5 demonstration runs and process transfer. Continue assay development and validation. - Begin animal immunogenicity studies and non-clinical testing. - Initiate bulk stability, container stability, and reconstitution stability testing on pilot lot.	Plague Vaccine - Continue stability testing and initiate animal testing. - Complete toxicology and immunogenicity testing. - Manufacture cGMP pilot lot and 3 qualification lots. - Funds the preparation and submission of an IND application. Conduct Phase I trials, higher animal species studies and perform animal efficacy studies on the UK product in order to collect data for a down-select decision.

FY 2003 Targets	FY 2004 Targets
Next Generation Anthrax Vaccine - Continue process definition work for a candidate recombinant protective antigen NGAV. - Manufacture and characterize master cell and working cell banks. - Conduct assay development and validation Initiated technology transfer and process definition for a candidate recombinant protective antigen NGAV. - Initiate cGMP pilot lot production. - Initiate product stability studies. - Conduct Clinical Phase I trial.	Next Generation Anthrax Vaccine - Continue product stability studies. - Complete manufacturing process development and cGMP pilot lot production. - Conduct manufacturing formulation optimization studies.
Smallpox Vaccine - Continue Smallpox and Vaccinia Immune Globulin (VIG) stability studies. - Complete 4th and 5th stages of a Phase I Clinical Trial (safety and immunogenicity). - Complete Process optimization and lot manufacture validation. - Produce three consistency lots, achieving first-year baseline stockpile quantities (4 million doses). - Submit IND annual reports and manufacturing amendments for Smallpox vaccine and VIG.	- n/a (transition to procurement)

2.4.23 *Performance Goal 4.12* Provide individuals and medics with post-treatments for BW agents.

Current Materiel Solutions	Future Materiel Solutions
Antibiotics (Service O&M responsibility)	Broad spectrum antibiotics Antitoxins Anti-viral drugs

2.4.24 Materiel Solutions Performance Measurements

2.4.24.1 Current R&D Targets

FY 2001Targets	Actual Performance
- Technology base efforts	- Technology base efforts Described in Section 3.0 (Projects TB2 and TB3)

2.4.24.2 Future R&D Targets

FY 2002 Targets	FY 2003 Targets
- Technology base efforts	- Technology base efforts

2.5 OPERATIONAL GOAL 5: MAINTAIN GROUND, AIR AND MARITIME OPERATIONAL TEMPO

2.5.1 *Performance Goal 5.1* Provide crewmembers with a limited capability to reduce the level of contamination on vehicles and weapon systems.

Current Materiel Solutions	Future Materiel Solutions
M11 Decon App, Portable (Legacy system) M13 Decon App, Portable (Legacy system) (both with DS-2)	M100 Sorbent Decon System (SDS)

2.5.2 Materiel Solutions Performance Measurements

2.5.2.1 Current Procurement Targets –M100 Sorbent Decon System

Systems	FY02		FY03	FY04
	Target	Actual	Target	Target
M100 Sorbent Decon System	120,000 [120,000 of 1,120,544]	140,000 [140,000 of 1,120,544]	130,000	0

2.5.3 *Performance Goal 5.2* Provide an operational capability to reduce the level of contamination on vehicles and weapon systems.

Current Materiel Solutions	Future Materiel Solutions
M17A2 Lightweight Decon System (Legacy System)	Modular Decon System (MDS)

2.5.4 Materiel Solutions Performance Measurements

2.5.4.1 Current Procurement Targets – MDS and JSFDS

Systems	FY02		FY03	FY04
	Target	Actual	Target	Target
Modular Decontamination System	27 [130 of 465]	96 [0 of 465]	101*	128
Joint Service Family of Decontaminant Systems (JSFDS)	67,030	71,355	90,000	392,000

2.5.5 *Performance Goal 5.3* Ensure vehicles, vans and ships have a protected environment that keeps NBC hazards out.

Current Materiel Solutions	Future Materiel Solutions
Various Gas-Particulate Filter Unit (GPFU) configurations (Legacy systems) Modular Collective Protection Equip. (Legacy systems) Selected Area CPS, Ship CPE, (Legacy systems) Ship CPS Backfit	Joint CP Equipment (JCPE) Shipboard Collective Protection Equipment (SCPE)

2.5.6 Materiel Solutions Performance Measurements

2.5.6.1 Current Procurement Targets – Ship CPS Backfit

Systems	FY02		FY03	FY04
	Target	Actual	Target	Target
Ship CPS Backfit (protective zones backfitted)	6 [17 of 51 procured]	5 [16 of 51 procured]	8	5

2.5.6.2 Current R&D Targets – Joint Collective Protection (CP) Equipment

FY 2002 Targets	Actual Performance
- Initiate development and testing of two types of improved COTS LP HEPA filters to extend filter life and improve performance. - Test ten improved M48A1 and M56 carbon filter with live agents to complete qualification of filter design. - Complete development of a single pleatable charcoal/HEPA bonded filter to replace two CB filters used in CP systems to reduce installation time, logistics, and cost.	- Initiated development and testing of one improved recirculation filter unit to reduce logistics costs. Initiated development and testing of noise reduction and abatement for CB shelter systems utilizing sound barriers. Initiated testing of 30 in service 100/200 Cubic Feet per Minute (CFM) gas filters to determine service life. Initiated testing of ten improved 100/200 CFM gas filters with live agents to complete qualification of filter design. Initiated development and testing of 2000 CFM particulate filters to reduce logistics costs. Completed development and testing of a pleat-

FY 2002 Targets	Actual Performance
- Conduct testing of RFU acceptance tester. RFU is designed to eliminate low level contamination brought into collective protection systems by personnel or equipment. - Increase efficiency of CPS supply fans by developing a variable speed air supply system to allow the CPS system to operate at peak performance over the entire range of filter loading. - Complete development and testing of FFA 400-100 and M93 candidate motorblowers for CB shelter systems to improve efficiency, reliability, size, and weight. - Complete development of the universal NBC ECU adapter that can apply a transportable cooling coil to the FFA 580 blower and other FFA blower configurations. - Initiate development of a new Air Force shelter configuration which combines a medium size shelter between two small shelters using a M28 collective protection liner.	able charcoal HEPA bonded filter to replace two CB filters used in collective protection systems to reduce installation time, logistics, and cost. - Completed study investigating the viability of permanent bar magnet and variable speed drives to improve the efficiency of shipboard Collective Protective System (CPS) supply fan motors to allow the CPS system to operate at peak performance over the entire range of filter loading. Completed development and testing of Fan Filter Assembly (FFA) 400-100 and M93 Modular Collective Protection Equipment (MCPE) candidate motorblowers for CB shelter systems to improve efficiency, reliability, size, and weight. Initiated development and testing of automatic power transfer switch for CP Expeditionary Medical Support (CPEMEDS). Completed development and testing of a modified ECU for CPEMEDS to allow rapid deployment of a reduced weight and size unit. Initiated design and test of CP modification kit for fielded heater systems. Initiated design and testing to reduce the CB filter blower heat load. Initiated study to investigate Environmental Control Unit (ECU) and power applications to CP shelters. - Initiated development of a modified M28 liner for large capacity shelters. Initiated design and testing of the thermal efficiency of CB protected shelter systems. Initiated testing of CB liners for long term storage in temperature extremes and alternate seam configurations. Initiated development and testing a CB liner seam tester. Initiated development and testing of an improved repair process for CB liners. Initiated design and testing of an improved liner material, construction, and enclosures. - Initiated developmental prototypes of a suite of improved airlocks to reduce purge times and simultaneous entry/exits for all existing CB shelter systems. Initiated study to determine the contamination control area requirements that meet NATO standards. Initiated development of logistical support plan for prior JCPE items. Initiated the system engineering of capability sets with improved components. Continue development and testing of a CP latrine for CPEMEDS.

2.5.6.3 Future R&D Targets – Joint Collective Protection (CP) Equipment

FY 2003 Targets	FY 2004 Targets
- Complete development of 2000 CFM particulate filters to reduce logistics costs. Complete live agent testing of improved 100/200 CFM gas filters. Complete development and testing of one improved recirculation filter unit to reduce logistics costs. Complete development and testing of noise reduction and abatement for CB shelter systems utilizing sound barriers. Complete testing of 30 in service 100/200 CFM gas filters to determine service life. Complete design and testing of the thermal efficiency of CB protected shelter systems - Perform development and testing to increase efficiency of CPS supply fan motors to operate at peak performance over the entire range of filter loading. Continue developmental prototypes of a suite of improved airlocks to reduce purge times and provide simultaneous	- Complete development and testing to increase efficiency of CPS supply fan motors to operate at peak performance over the entire range of filter loading. Initiate development of shipboard CP improvements to reduce total operating costs. - Complete testing of developmental prototypes of a suite of improved airlocks to reduce purge times and simultaneous entry/exits for all existing CB shelter systems.

FY 2003 Targets	FY 2004 Targets
entry/exits for all existing CB shelter systems. Complete study to determine the contamination control area requirements that meet NATO standards. Complete development of logistical support plan for prior JCPE items. Continue the system engineering of capability sets with improved components. - Complete development of a modified M28 liner for large capacity shelters. Continue design and testing of an improved liner material, construction, and enclosures. Complete development and testing of automatic power transfer switch for CPEMEDS. Complete design and test of CP modification kit for fielded heater systems. Complete design and testing to reduce the CB filter blower heat load. Complete study to investigate ECU and power applications to CP shelters. Continue testing of CB liners for long term storage in temperature extremes and alternate seam configurations. Complete development and testing a CB liner seam tester. Complete development and testing of a improved repair process for CB liners. Complete development and testing of a CP latrine for CPEMEDS.	Complete design and testing of an improved liner material, construction, and enclosures. - Complete testing of CB liners for long term storage in temperature extremes. Initiate development and testing of 10 modified 100/200 CFM gas filters to provide Toxic Industrial Chemicals (TICs) protection. Complete the system engineering of capability sets with improved components.

2.5.6.4 Current R&D Targets – Shipboard Collective Protection (SCPE)

FY 2002 Targets	Actual Performance
- Continue shipboard testing of improved CPS fan. Shipboard testing is required to verify actual noise reduction in a fan room and adjacent manned spaces on board a ship. Use test data to revise CPS fan rotor performance specification. Improved CPS fan rotors will increase efficiency and reduce noise levels by 12 to 17 decibels. - Complete third year of verification testing to validate the four-year performance of improved prefilters and HEPA filters. - Continue evaluation of HEPA filter performance degradation after TIC/TIM exposure. - Continue development and testing of two electronic differential pressure gauges for remote reading to reduce shipboard maintenance. - Prepare and update documentation (test reports, Tech Manuals and TDP). Initiate transition of selected efforts to JCPE.	- FY 02 targets met. - Continued shipboard testing of improved CPS fan rotor to verify actual noise reduction in a fan room and adjacent manned spaces on board ship. Revised CPS fan rotor performance specification. Improved CPS fan rotors to increase efficiency and reduce noise levels by 12 to 17 decibels. Completed third year of verification testing to validate the four-year performance of improved prefilters and HEPA filters. Began testing and evaluation of HEPA filter performance degradation after TIC/ TIM exposure. Continued development and testing of two electronic differential pressure gauges for remote reading to improve shipboard CPS maintenance. - Completed third year of verification testing to validate the four-year performance of improved prefilters and HEPA filters. Began testing and evaluation of HEPA filter performance degradation after TIC/TIM exposure. - Continued development and testing of two electronic differential pressure gauges for remote reading to improve shipboard CPS maintenance.

2.5.6.5 Future R&D Targets – Shipboard Collective Protection (SCPE)

FY 2003 Targets	FY 2004 Targets
- Complete shipboard testing of improved CPS fan rotors. Test data will be used to revise CPS fan rotor performance specification. Complete final year of verification testing to validate the four-year performance of improved prefilters and HEPA filters. Complete testing and evaluation of HEPA filter performance degradation after TIC/TIM exposure. Complete development and testing of two electronic differential pressure gauges for remote reading to improve shipboard CPS maintenance.	- n/a (transition to procurement)

2.5.7 *Performance Goal 5.4* Provide a hazard-free environment for mobile command and control operations.

Current Materiel Solutions	Future Materiel Solutions
M20A1 SCPE (Legacy system) Portable CPS (Legacy system)	Joint Transportable Collective Protection Shelter (JTCOPS) Block I Joint CP Equipment

2.5.8 Materiel Solutions Performance Measurements

2.5.8.1 Current R&D Targets – Joint Transportable Collective Protection Shelter Block I

FY 2002 Targets	Actual Performance
- Award development contract for Block I. - Conduct entire design phase of the contract and begin the prototype fabrication phase.	- Continued preparation of program documentation including the Single Acquisition Management Plan, the System Requirements Document, and the Life Cycle Cost Assessment. Continued engineering support, and conducted program management activities.

2.5.8.2 Future R&D Targets – Joint Transportable Collective Protection Shelter Block I

FY 2003 Targets	FY 2004 Targets
- Release a Request for Proposals, evaluate proposals and award a development contract. Begin the design phase of the program.	- n/a (Preparing for transition to procurement.)

2.5.8.3 Current & Future R&D Targets: Joint CP Equipment (see §2.5.6.2 and §2.5.6.3)

2.6 OPERATIONAL GOAL 6: SUSTAIN OPERATIONS, RECOVERY AND RECONSTITUTION EFFORTS

2.6.1 *Performance Goal 6.1* Provide units with a capability to eliminate all contamination on vehicles and weapon systems.

Current Materiel Solutions	Future Materiel Solutions
M12 Power-Driven Decon Apparatus (Legacy system)	Modular Decon System (MDS)

2.6.2 Materiel Solutions Performance Measurements

2.6.2.1 Current & Future Procurement Targets – Modular Decon System (see §2.5.4)

2.6.3 *Performance Goal 6.2* Provide units with a capability to eliminate all contamination on terrain and fixed sites.

Current Materiel Solutions	Future Materiel Solutions
M12 Power-Driven Decon Apparatus (Legacy system)	Joint Service Family of Decontamination System (JSFDS) - Blocks I, II, and III

2.6.4 Materiel Solutions Performance Measurements

2.6.4.1 Current R&D Targets – Joint Service Family of Decontamination Systems (JSFDS)

FY 2002 Targets	Actual Performance
- Continue toxicology testing and other evaluations necessary for FDA approval to support downselect of Block III skin/casualty decontaminants. - Award PDRR contract(s) for Block II family of applicators system to develop prototype applicator and containment systems for evaluation (15 systems	- Completed development of standard test operating procedures and the Test and Evaluation Master Plan (TEMP) for Block I decontaminants. Updated program documentation to support a Milestone (MS) B decision. - Conducted market survey of commercial products

FY 2002 Targets	Actual Performance
at average cost of $100K) - Perform Early Operational Assessment and initiate DT of Block II family of applicator systems. - Complete DT/OT on family of decontaminants for Block I. Complete MS C documentation for Block I. - Incorporate lessons learned from Operational Testing (OT) into logistics support documentation for Block I family of decontaminants. - Prepare documentation and test reports, conduct downselect of medical/skin decontamination in support of Block III SDD contract award.	that could satisfy Block II applicator and containment systems. Initiated development of Block II systems performance specifications. - Evaluated proposals, downselected proposed Block III skin decontamination products to undergo Development Test and Evaluation I (DT I) for selecting the proposals for contract award. - Conducted DT I efficacy testing for neutralization and removal of chemical and biological agents. - Initiated DT I animal safety studies and preliminary animal efficacy studies. - Conducted Developmental Testing (DT) of the decontaminant to satsify CENTCOM UNS, including chemical and biological live agent, environmental compatibility and packaging tests. - Conducted OT of the decontaminant to satisfy CENTCOM UNS. - Conducted detail test planning, program support, environmental and safety studies.

2.6.4.2 Future R&D Targets – Joint Service Family of Decontamination Systems (JSFDS)

FY 2003 Targets	FY 2004 Targets
- Complete OT report for decontaminant to satisfy CENTCOM UNS. - Complete Developmental Test and Evaluation (DT&E) animal safety studies and preliminary animal efficacy studies for Block III skin decontaminants. - Conduct detail test planning and procure decontaminants for testing for Block I (approximately 8,000 gallons at average cost of $18 per gallon). - Initiate OT&E for Block I to support a Milestone III. - Conduct DT I and initiate DT II test for Block I decontaminant and update program documentation. Conduct optimization/feasibility testing of various forms of applying Block I decontaminants to support Block II performance specifications development. - Initiate DT II for Block III Skin decontaminants to generate data to support Food and Drug Administration (FDA) approval.	- Finalize TEMP for Block II. Evaluate proposals, conduct system demonstration, and select proposal for contract award. Update program documentation and conduct MS B. - Initiate Market and Technology Transition survey(s) for Block IV efforts to identify solutions for unmet JSFDS requirements including means to expedite casualty process, means to decontaminate Toxic Industrial Materials (TIMs) and additional agents. Develop acquisition strategy to address Block IV. - Develop a test strategy to downselect Block IV products for Demonstration. Initiate the development of standard operating procedures and conduct testing to validate the test methodology for Block IV. - Complete Operational Testing and Evaluation (OT) for Block I to support a procurement decision. - Procure Block II applicator and containment systems for Lab testing and Operational Assessment (AO) (200 systems at average cost of 25K each). - Conduct lab testing and operational assessment and downselect the candidates to take to DT/OT. - Procure Block II applicator and containment systems for DT testing (45 systems at average cost of 36K). - Continue DT II testing of Block III skin decontaminants to generate data to support FDA approval.

2.6.5 *Performance Goal 6.3* Provide units with a capability to eliminate all contamination on sensitive equipment and avionics.

Current Materiel Solutions	Future Materiel Solutions
None	Joint Service Sensitive Equipment Decon System (JSSEDS) Block I

2.6.6 Materiel Solutions Performance Measurements

2.6.6.1 Current R&D Targets – JSSEDS Block I

FY 2002 Targets	Actual Performance
- Award Block I Competitive Contract. - Evaluate Block I prototypes during competitive "shoot-off" to determine decontamination efficacy.	- Awarded Block I competitive contract to deliver three system models from selected contractor and investigate design improvements to meet military requirements. Total of three prototypes at $150K each. - Initiated prototype testing.

2.6.6.2 Current R&D Targets – JSSEDS Block I

FY 2003 Targets	FY 2004 Targets
- Conduct Block I program Interim Progress Review (IPR) to finalize Block I technology and system design. - Award contract to develop and fabricate Block I developmental test systems (eight items at $300K each) which implement design improvements from the prior year prototypes. - Initiate pre-production Block I system test design.	- Continue fabrication of developmental test hardware for Block I (12 test items estimated at $300K each). - Initiate conduct of trade-off evaluation for Block I final system.

2.6.7 *Performance Goal 6.4* Provide units with a capability to eliminate all contamination on vehicle/aircraft interiors

Current Materiel Solutions	Future Materiel Solutions
None	Joint Service Sensitive Equipment Decon System (JSSEDS) - Blocks II and III

2.6.8 Materiel Solutions Performance Measurements

2.6.8.1 Current R&D Targets – JSSEDS Blocks II and III

FY 2002 Targets	Actual Performance
- Technology base efforts	- See Section 3.0

2.6.8.2 Current R&D Targets – JSSEDS Blocks II and III

FY 2003 Targets	FY 2004 Targets
- Prepare and submit Block II/III Milestone B documentation, which includes Test and Evaluation Master Plan, System Acquisition Master Plan, and Acquisition Program Baseline. - Prepare Request for Proposal for Block II/III combined development effort.	- Award system development and demonstration contract for Block II and build prototypes (20 test items estimated at $300K each).

2.6.9 *Performance Goal 6.5* Monitor the presence/absence of CW agent contamination after decon.

Current Materiel Solutions	Future Materiel Solutions
Chemical Agent Monitor (CAM) (Legacy system) Improved CAM (ICAM)	Joint Chemical Agent Detector

2.6.10 Materiel Solutions Performance Measurements

2.6.10.1 Current Procurement Targets – ICAM

(Fielded system. No planned procurement.)

2.6.10.2 Current & Future R&D Targets – JCAD (See §2.2.4.1 and §2.2.4.2)

2.6.11 *Performance Goal 6.6* Monitor the presence/ absence of CW agent contamination in water.

Current Materiel Solutions	Future Materiel Solutions
M272A1 Water Test Kit (Service O&M responsibility)	Joint CB Agent Water Monitor (JCBAWM)

2.6.12 Materiel Solutions Performance Measurements

2.6.12.1 Current R&D Targets – Joint CB Agent Water Monitor (JCBAWM)

FY 2002 Targets	Actual Performance
- Science & Technology base (S&T) effort	- Technology base efforts Described in Section 3.0

2.10.12.2 Future R&D Targets – Joint CB Agent Water Monitor (JCBAWM)

FY 2003 Targets	FY 2004 Targets
- Pending transition from S&T	- Pending transition from S&T

2.6.13 *Performance Goal 6.7* Provide a hazard-free environment for long-term command and control operations.

Current Materiel Solutions	Future Materiel Solutions
Fixed Site CPS (Legacy system)	Joint CP Equipment Joint Transportable CP Shelter (JTCOPS)

2.6.14 Materiel Solutions Performance Measurements

2.6.14.1 Current & Future R&D Targets – Joint Collective Protection (CP) Equipment (see § 2.5.6)

2.6.14.2 Current & Future R&D Targets – Joint Transportable CP Shelter (JTCOPS) (See §2.5.7 and §2.5.8)

2.6.15 *Performance Goal 6.8* Provide a hazard-free environment for forward tactical medical operations.

Current Materiel Solutions	Future Materiel Solutions
M51 Shelter (Legacy system) CB Protective Shelter (CBPS)	Joint CP Equipment JTCOPS CBPS P3I

2.6.16 Materiel Solutions Performance Measurements

2.6.16.1 Current Procurement Targets – CBPS

	FY02		FY03	FY04
Systems	Target	Actual	Target	Target
CBPS	32 [164 of 1,224 procured]	35 [167 of 1,224 procured]	37	0

2.6.16.2 Current and Future R&D Targets – Joint CP Equipment (see §2.5.7)

2.6.16.3 Current and Future R&D Targets – JTCOPS (see §2.5.7)

2.6.16.4 Current R&D Targets – CBPS P3I

FY 2002 Targets	Actual Performance
- Develop design concept for CBPS airborne and heavy versions. - Coordinate with user and field representatives on requirements and logistics supportability. - Award a three phase contract for design and fabrication of a self-powered Environmental Support System (ESS). - Award Phase I in FY 2002 to develop an ESS that will meet the requirements for CBPS-light, heavy, and airborne versions. - Fabricate one prototype and conduct initial performance and reliability testing.	- FY 02 targets met - Initiated design concept for CBPS airborne and heavy versions, and interfaces with non-HMMWV platforms that are suitable for airborne and other applications. Coordinated with user and field representatives on requirements and logistics supportability. Developed Scope of Work (SOW) for design and fabrication of ESS. - Awarded contract for design and fabrication of a self-powered ESS that will meet the requirements for CBPS-light, heavy, and airborne versions. Continued development of virtual prototype and limited Technical Data Package.

2.6.16.5 Future R&D Targets – CBPS P3I

FY 2003 Targets	FY 2004 Targets
- Fabricate two ESS prototypes at unit cost of $250K, finalize design and complete Technical Data Package. - Conduct performance testing on one ESS prototype. - Finalize design concept for ESS and document in technical data package. Integrate ESS onto non-vehicle based platform. Manage CBPS P3I.	- Program stopped pending completion of MAA and reassessment of the ORD.

2.6.17 *Performance Goal 6.9* Provide a hazard-free environment for long-term rear-area medical operations.

Current Materiel Solutions	Future Materiel Solutions
CP DEPMEDS/CHATH	Joint Transportable Collective Protection System (JTCOPS)

2.6.18 Materiel Solutions Performance Measurements

2.6.18.1 Current Procurement Targets – CP DEPMEDS/CHATH

	FY02		FY03	FY04
Systems	Target	Actual	Target	Target
CP DEPMEDS/ CHATH	3 [14 of 23 procured]	2 [13 of 23 procured]	0	0

2.6.18.2 Current and Future R&D Targets – JTCOPS (see §2.5.7)

2.6.19 *Performance Goal 6.10* Develop medical identification and diagnosis device capable of identifying multiple BW agents in clinical and environmental sources.

Current Materiel Solutions	Future Materiel Solutions
None (interim measure- manual medical diagnoses and Theater Army Medical Labs)	Joint Biological Agent Identification and Diagnostic System (JBAIDS)

2.6.20 Materiel Solutions Performance Measurements

2.6.20.1 Current R&D Targets – JBAIDS

FY 2002 Targets	Actual Performance
- Initiate design improvements of units transitioning from DTO and begin fabrication of EDT units. - Conduct EDT. - Initiate submission of Identification Assays to the FDA for regulatory approval. - Initiate Integrated Logistics Support analysis development and technical drawings package requirements. - Initiate development of technical manuals.	- Conducted full and open competition to select winning JBAIDS contractor; four phased-down selection process used. Fourteen contractors initially evaluated, seven asked to participate in "Fly-Off/laboratory test of performance capabilities. - Conducted laboratory test at Dugway Proving Grounds, UT. Two contractors passed the test and will receive RFPs. Objective was to ensure "low risk", short development program in FY03, and rapid fielding in FY04. - Completed DoD Acquisition documentation requirements.

2.6.20.2 Current R&D Targets – JBAIDS

FY 2003 Targets	FY 2004 Targets
- Select winning contractor from the remaining two candidate "fly-off" tested designs. - Purchase 25 development prototype JBAIDS and 128,000 test assay kits to support development and operational testing (OT) requirements. - Conduct development testing at contractor's facility and government laboratories. Conduct JBAIDS hardware reliability and environmental testing. - Submit JBAIDS agent (anthrax and 2 targets) 510K package for FDA review and clearance. - Review contractor developed JBAIDS technical manuals, review training packages, complete system drawing requirements to support a physical configuration audit of the design.	- Complete OT programs. - Submit additional 9 JBAIDS BW agents identification test assays (510K packages) to FDA for review and clearance.

SCIENCE AND TECHNOLOGY BASE PERFORMANCE GOALS AND MEASURES

3.0 OVERVIEW

The science and technology base (S&T) of the Chemical and Biological Defense Program provides essential capabilities to develop technological advantage over any potential adversaries and prevent technological surprise. Within S&T there are three budget activities and three research areas, and project funding codes for each. (See Table 1.)[2]

Table 1. CBDP Science and Technology Base Project Funding Codes

	Research Area		
	Non-Medical S&T	Medical S&T	
Budget Activity (Program Element)	**CB Defense**	**Chemical Defense**	**Biological Defense**
BA1 - Basic Research (0601384BP)	CB1	TC1	TB1
BA2 - Applied Research (0602384BP)	CB2	TC2	TB2
BA3 - Advanced Technology Development (0603384BP)	CB3, CP3, and CM3	TC3	TB3

The approach for identifying and developing quantitative performance goals and measures on an annual basis is not always well suited for evaluating the progress of S&T efforts. The long term nature of many of these efforts makes the identification of quantitative measures on an annual basis meaningless (for example, how many breakthroughs in basic science were made last year.) However, using an approach similar to those used in the performance plans of other federal research centers—including the National Academies of Science, the National Institutes of Health, and the National Science Foundation—there are a variety of qualitative and quantitative performance measures that may be used to demonstrate progress of S&T efforts towards outcomes, which fulfills the requirements of the GPRA.

The basic performance measure established for S&T efforts is the independent expert panel review. The CBDP has adopted this practice using an independent panel of scientists from outside the Department to provide an assessment of the funding and research areas within the program. This process, known as the Technology Area Review and Assessment (TARA), has been conducted annually by the CBDP. The TARA panel provides a presentation of their findings and recommendations to the Defense Science and Technology Advisory Group, the senior leaders within the Department responsible for S&T within DoD.

3.1 CB DEFENSE S&T PLANNING

To ensure U.S. military preeminence in the long term, the Department must continue to focus investments on new generations of defense technologies. The Defense Science and Technology Strategy, with its supporting Basic Research Plan, Joint Warfighting Science and Technology Plan, and Defense Technology Area Plan, is the foundation of the science and technology (S&T) program. The Office of the Secretary of Defense, the Joint Staff, the military departments, and the defense agencies collaboratively develop the S&T program. Objectives of S&T planning are to:

- ensure projects support warfighter requirements,
- identify gaps in existing defense and commercial research,
- ensure collaborative planning and execution of the S&T program,

[2] Biological Warfare Defense programs funded under DARPA project BW-01 are not addressed in this performance plan except for those projects identified as Defense Technology Objectives.

- reduce undesired duplication of effort,
- provide the basis for independent expert panel reviews.

3.2 DOD CB DEFENSE SCIENCE AND TECHNOLOGY BASE PROGRAM

This section provides the objectives and metrics for the overall CB defense S&T program. An overall assessment is provided below. Actual and planned performance on specific projects is detailed in the following sections on S&T.

3.2.1 CB Defense Science and Technology Outcome Measure

CB Defense S&T is… …minimally effective when…	… successful when…
• All major commodity areas are rated GREEN and no sub-areas are rated RED by the TARA panel. • Research efforts contribute to increased knowledge regarding CB threats and science and technologies to defend against these threats. • Projects support goals and timelines stated in planning documents, specifically the *Joint Warfighting Science and Technology Plan* and the *Defense Technology Area Plan*.	• All commodity areas are rated GREEN by the TARA panel. • New capabilities are successfully demonstrated and transition to advanced development.

3.2.1.1 Metric Description. The metric for science and technology base projects is a qualitative assessment of the results of basic research, applied research, and advanced technology development compared to their intended purposes. This qualitative methodology for measuring the outcomes of the science and technology base is allowed by the GPRA (31 USC 1115(b)) as an alternative to the quantitative performance measures. The approach for identifying and developing quantitative performance goals and measures on an annual basis is not always well suited for evaluating the progress of research efforts. The long term nature of many of these efforts makes the identification of quantitative measures on an annual basis meaningless (for example, how many breakthroughs in basic science were made last year.) This approach is similar to those used in the performance plans other federal research centers—including the National Academies of Science, the National Institutes of Health, and the National Science Foundation. Qualitative performance measure are provided for each of the projects listed in table 1. Qualitative performance measures are assessed by an independent panel as well as by the accomplishment of specific project targets identified and detailed in each of the project areas below. The assessment includes an evaluation of the information provided to determine whether it is sufficient to allow for an accurate, independent determination of the program activity's performance. An important element of the research efforts—especially for basic and applied research—is the evaluation and elimination of unsuccessful technologies. While not always identified as a specific target, the scientific method contributes to increased knowledge by eliminating efforts that will not contribute to project objectives.

3.2.1.2 Validation and Verification Methodology. The basic performance measure established for S&T efforts is the *independent expert panel review*.[3] This is in keeping with White House guidance to ensure that independent assessments of research programs evaluate

[3] *Evaluating Federal Research Programs: Research and the Government Performance and Results Act*, Washington, D.C: National Academy Press, 1999.

both the quality of programs and progress of research towards stated goals.[4] The CBDP has adopted this practice using an independent panel of scientists from outside the Department to provide an assessment of the funding and research areas within the program. This process, known as the Technology Area Review and Assessment (TARA), is conducted annually by the CBDP. The TARA panel provides a presentation of their findings and recommendations to Defense Science and Technology Advisory Group, the senior leaders within the Department responsible for S&T within DoD. Table 2 provides a summary of the assessment of each of the commodity areas within the CBDP, and table 3 provides the assessment by the TARA Panel of each of the DTOs presented during the FY2002 review.

Table 2. 2002 TARA Assessment of CB Defense S&T Commodity Areas

CB Defense Science and Technology Commodity Area	*TARA Rating*
DETECTION	GREEN
– Point Detection	YELLOW
– Standoff Detection	GREEN
PROTECTION	GREEN
– Non-Medical	GREEN
– Individual Protection	GREEN
– Collective Protection	GREEN
– Medical	GREEN
– Medical Chemical Defense	GREEN
– Medical Biological Defense	YELLOW
DECONTAMINATION	GREEN
INFORMATION SYSTEMS TECHNOLOGY	GREEN

3.2.2 Assessment of CB Defense Science and Technology Outcome Measure

Overall, the DoD CBDP science and technology base has been effective. Most areas have been rated green by the TARA panel. In addition, there were several technologies that completed successful demonstrations over the past year, and as detailed in the following sections, there are several examples of technology transitions to advanced development.

3.3 DEFENSE TECHNOLOGY OBJECTIVES

The Department's commitment to transforming U.S. military forces requires robust and stable funding for the S&T program. S&T expenditures support basic research as well as focused investments guided by defense technology objectives (DTOs). DTOs provide a framework for S&T efforts by identifying:

- What specific technologies will be developed and/or demonstrated.
- What specific milestones are to be reached, using what approaches.
- Which customers will benefit.
- What specific benefits the customers will gain.
- What level of funding will be programmed and from what sources.
- What quantitative metrics will indicate progress.

[4] See memorandum from The White House, Neal Lane and Jacob J. LE, "Follow-On Guidance for FY 2001 Interagency Research and Development Activities," June 8, 2000.

Within the CBDP, DTOs fund approximately one-third of S&T efforts. DTOs are the building blocks of the defense S&T Program. They represent only high priority Service and Defense Agency programs, consistent with the Defense Planning Guidance and the Defense S&T Strategy. DTOs are one of the key S&T planning tools. They are used to assist in planning and programming S&T funds, they help in articulating key efforts and goals, and they provide a key performance measure for contribution of the S&T effort to warfighter needs. All updates, changes, and approvals of DTOs are made by the Defense Science and Technology Advisory Group (DSTAG), the senior S&T advisory body within the Department. Assessments of DTO performance are provided annually by the TARA.

The CBDP S&T efforts continue to demonstrate new capabilities for the warfighter. Progress of DTOs is shown in the following tables. Progress in other portions of S&T is shown in section 3.4. For FY2002, 58% of the DTOs were rated green, which was less than the target of 80%. Several factors contributed to these ratings, including: (1) pursuit of leading edge research, which included accepting technical risks on several projects, (2) aggressive scheduling of milestones by the DTO managers, and (3) more realistic assessment of costs, schedules, and technical performance by the TARA panel. The TARA Panel made specific recommendations on each of the DTOs that were not rated green, and they will review and assess these efforts in FY2003.

3.3.1 Performance Indicator – Status of Defense Technology Objectives as Rated by the Chemical and Biological Defense Technology Area Review and Assessment

	FY2002		FY2003	FY2004
	Goal	Actual	Goal	Goal
Percent of DTOs Rated Green (on track)	80	58*	80	80
Total Number of DTOs	25 of 31	18 of 31*		

* Ten CBD DTOs were rated as yellow [Y] and three as red [R]

Table 3. 2002 TARA Rating of Chemical and Biological Defense DTOs

DTO No.	DTO Title	*TARA Rating*
I.03	Restoration of Operations ACTD.	YELLOW
I.04	Contamination Avoidance at Seaports of Debarkation ACTD	YELLOW
CB.08	Advanced Adsorbents for Protection Applications	GREEN
CB.09	Enzymatic Decontamination	GREEN
CB.19	Chemical Imaging Sensor	**GREEN**
CB.20	Biological Sample Preparation System for Biological Identification	YELLOW
CB.24	Medical Countermeasures for Encephalitis Viruses	**GREEN**
CB.25	Multiagent Vaccines for Biological Threat Agents	**GREEN**
CB.26	Common Diagnostic Systems for Biological Threats and Endemic Infectious Diseases	**YELLOW**
CB.27	Therapeutics Based on Common Mechanisms of Pathogenesis	YELLOW
CB.28	Chemical Agent Prophylaxes II	GREEN
CB.29	Active Topical Skin Protectant	GREEN
CB.30	Medical Countermeasures for Vesicant Agents II	**GREEN**
CB.31	Medical Countermeasures for Brucellae	**YELLOW**
CB.32	Needle-less Delivery Methods for Recombinant Protein Vaccines	**GREEN**
CB.33	Recombinant Protective Antigen Anthrax Vaccine Candidate	**YELLOW**
CB.34	Recombinant Plague Vaccine	**YELLOW**
CB.35	Standoff Biological Aerosol Detection	GREEN

DTO No.	DTO Title	*TARA Rating*
CB.36	Universal End-of-Service-Life Indicator for NBC Mask Filters	GREEN
CB.37	CB Agent Water Monitor	YELLOW
CB.38	Activity-Based Detection and Diagnostics	GREEN
CB.39	CW/BW Agent Screening and Analysis	RED
CB.40	Immune Building Program	GREEN
CB.41	Biological Warfare Defense Sensor Program	YELLOW
CB.42	Environmental Fate of Agents	GREEN
CB.43	Chemical and Biological Warfare Effects on Operations	RED
CB.44	Oxidative Decontamination Formulation	GREEN
CB.45	Self-Detoxifying Materials for Chemical/Biological Protective Clothing	GREEN
BE.10	High-Resolution Meteorological Nowcasting for Chemical/Biological Hazard Prediction	GREEN
L.12	Force Medical Protection/Dosimeter ACTD	RED

3.3.1.1 Metric Description. Table 3 lists specific DTOs assessed during 2002. Detailed descriptions of these DTOs are found in The DoD CBDP Annual Report to Congress, Annexes A–E. Each DTO is reviewed annually by an independent peer review panel, called the Technology Area Review and Assessment (TARA) panel. The goal is to have at least 80% of the DTOs rated green. The total number of DTOs varies per year based on new DTO assignments and completion of DTO efforts. Total DTO funding varies per year and may represent between 25%–50% of total science and technology base funds. During the 2002 TARA, ten CBD DTOs were rated as yellow and three as red. Following is a summary explanation for these ratings.

Table 4. Summary of Explanations for Selected 2002 TARA CB Defense DTOs

DTO	TARA Rating	Summary Explanation of TARA Rating
I.03 Restoration of Operations ACTD	YELLOW	•**Strengths:** –Good start to understand the scope of challenges to base commander •**Observations:** –Focus on sortie rate as the key metric may not be robust enough to define value of technology and/or TTP options –Need to more fully engage the experts in key areas –Focus on single threat dimension is not realistic and does not provide an optimal analysis framework •**Recommendation:** –Needs much more analysis of and emphasis on all dimensions of Consequence Management (e.g., medical functional area, quartermaster/mortuary affairs, environmental remediation, etc.)
I.04 Contamination Avoidance at Seaports of Debarkation ACTD	YELLOW	•**Strengths:** –Taking on an important and challenging issue. •**Observations:** –Operational issues will overwhelm technology issues. –Involvement of SMEs not apparent. •**Recommendation:** –Broad engagement of experts in multiple functional areas is critical –Focus on C2 and logistics planning technologies vice CB technologies

DTO	TARA Rating	Summary Explanation of TARA Rating
L.12 Force Medical Protection/Dosimeter ACTD	RED	•**Strengths:** –Identified that commercial passive collectors are usable for chemical threat agent collectors –Eliminated ICAS as a viable candidate technology •**Observations:** –Did not fully define a personal protection CONOPS –No general use residuals were produced. •**Recommendation:** –Do not continue effort
CB.20 Biological Sample Preparation System for Biological Identification	YELLOW	•**Strengths:** –Initial phase of DTO has already produced a reasonable improvement over manual preparation –Will work with both PCR technologies – Cepheid, RAPIDS •**Observations:** –Significant technological challenges in reducing sample preparation time –Need to address protocols and technologies for sampling environmental (*i.e.*, dirty/contaminated) samples –No RNA-based agents in the portfolio –RNA agents are rate limiting challenge •**Recommendations:** –Request "technology use" AoA with a feasible technology baseline to help focus the effort on critical technical barriers (such as sample preparation time or sample quality)
CB.26 Common Diagnostic Systems for Biological Threats and Endemic Infectious Diseases	YELLOW	• **Strengths:** –Despite delays, good overall progress. –Using pragmatic approach given limited commercial interest when project was initiated. • **Observations:** –Schedule at risk. Demands on personnel as a result on anthrax letter "attacks" resulted in schedule slip. *Resource fragility*: Limited depth of personnel means research projects may continue to be susceptible to operational or other demands. –DARPA contributions to effort not clear. –May be able to use different approaches by leveraging commercial technologies that have been developed in recent years. • **Recommendations:** –Schedule Risk: In order to complete DTO, limit scope of agents to be addressed.

DTO	TARA Rating	Summary Explanation of TARA Rating
CB.27 Therapeutics Based on Common Mechanisms of Pathogenesis	YELLOW	•**Strengths:** –Excellent innovative approaches. (Lytic enzymes, CpG) –Bridging study for anthrax to provide alternative NHP animal model –Soliciting FDA comments early. Anticipating NHP issue. •**Observations:** –Success is a mixed blessing. Program has produced capabilities in therapeutics with great potential for technology transition. DTO is bringing many products up to the transition phase without sufficient resources to allow for development of IND application. –Unrealistic expectation to have 6 products transition to IND in less than 2 years –Abrupt end in FY03 •**Recommendations:** –Closer coordination with CBDP needed to ensure realistic technology transition plans –Program would need to be extended to prepare selected candidates for IND submission
CB.31 Medical Countermeasures for Brucellae	YELLOW	• **Strengths:** –Progress made since last year. • **Observations:** –Budget and technical risks to complete all stated objectives on schedule. –Focus in research needed. Addressing 4 different species. –Requirement and priority defined by user not clear. –Poor characterization of pulmonary challenge. Surrogate (conjunctival) model appropriateness not clear. Not clear if model would be accepted by FDA to support approval of IND application. –Extrapolation from animal model to support FDA approval will be challenge. Many uncontrolled variables. • **Recommendations:** –Re-scope effort to complete within schedule and budget. May require addressing only one species.
CB.33 Recombinant Protective Antigen Anthrax Vaccine Candidate	YELLOW	• **Strengths:** –Broad program approach to all issues of IND data package submission –Anticipating technical issues • **Observations:** –Budget and technical risks to complete all stated objectives on schedule –Does not appear that essential echelons of management have deliberate process for program trades (*e.g.*, people, space, test animals) • **Recommendation:** –Deliberate management attention to regulatory approval requirements and exit criteria for transition

DTO	TARA Rating	Summary Explanation of TARA Rating
CB.34 Recombinant Plague Vaccine	YELLOW	•**Strengths:** –Commercialization, purity studies, selected predictive methods, criteria for lot release – Multi-angle Light Scatter (MALS) –Strong science base, good parametric approach •**Observations:** –Major technical challenges: surrogate marker (correlation of antibody titer level with protection not clearly established) –Data not coming out as expected. –Little schedule flexibility •**Recommendations:** –Consider a refocus on a pneumonic-only first generation vaccine (delay bubonic) –Ensure focus for assay characterization is limited – this may be deferred to advanced development
CB.37 CB Agent Water Monitor	YELLOW	• **Strengths:** –Commended for incorporating results of independent review. • Other programs would benefit from independent technology review early in program process • Developed realistic water backgrounds –Focus on CW agents (TICs no longer addressed) –Dual use capacity –Identified 6 candidate technologies –Surface-Enhanced Raman Spectroscopy (SERS) sensitivity improving • **Observations:** –Would like to see effort leverage work done by organizations with responsibility for protection water supplies (Corps of Engineers and relevant federal agencies) –Need to focus on technology evaluation and do not continue technology survey (may cause further schedule risk) –BW agent detection remains a challenge • **Recommendations:** –Focus. Re-scope to update schedule as proposed. Focus on threat agents.
CB.39 CW/BW Agent Screening and Analysis	RED	• **Observations:** –Objectives not clear, thus lacking criteria to rate for progress towards goals –Scientific and technical challenges not identified in presentation –Not well coordinated with other agencies developing technologies; MALDI effort appears to be duplicative of CB.41 BW Sensors –Appears program has not considered the technical challenges of being consistent with fielded systems performing similar functions (forensic and legal challenges) –Concepts not clear: mix of state-of-the-art (high sensitivity/specificity) and old technologies • **Recommendations:** –Re-evaluate objectives, scope, and investment. –Report to ATSD(NCB) with revised management plan that addresses requirements unique to treaty verification.

DTO	TARA Rating	Summary Explanation of TARA Rating
CB.41 Biological Warfare Defense Sensor Program	YELLOW	•**Strengths:** –Sound approach to tough technological problem. –Leveraging SBCCOM expertise •**Observations:** –Unclear whether MALDI will significantly contribute to solving the problem of bio detection specificity –Delivery of breadboard this late in schedule precludes timely and full evaluation. –Technology risk. Focus of effort is signal processing dependent on the development of a sensor (MALDI-TOF) that has not been demonstrated. •**Recommendations:** –Consider extension of the DTO if the breadboard proves successful. –Possible refocus to algorithm development supporting generic MALDI applications.
CB.43 Environmental Fate of Agents	RED	•**Observations:** –The question is critical, it needs to be answered, and achieving success will be difficult. –Question the experimental design and the protocol structure. –Intent of first principles model needs to be clarified •**Recommendations:** –Technical Director (ECBC) should recruit a group of nationally regarded experts for advice –Better program management needs to be addressed. –This effort will require an interdisciplinary approach, including soil science specialists, agronomists, concrete specialists, etc. –Re-write the DTO

3.3.1.2 V&V Methodology. Each TARA team includes about ten members, including experts from outside the Department. The non-DoD members include experts in relevant fields from other U.S. government agencies, private industry, and academia. S&T stakeholders (*e.g.*, senior S&T officials, the Joint Staff, and technology customers) attend the reviews as observers. TARA teams assess DTOs in terms of three factors—budget, schedule, and technical performance—and assign the programs a Red, Yellow, or Green rating based on how well they are progressing toward their goals. The assessment of technical performance includes a qualitative assessment of how risk is managed, especially for innovative or leading edge research that may involve high technical risk. This method of peer review is accepted and endorsed by the S&T stakeholders. Adjustments are made to program plans and budgets based on the ratings awarded. The following criteria are used in assigning ratings:

- Green – Progressing satisfactorily toward goals.
- Yellow – Generally progressing satisfactorily, but some aspects of the program are proceeding more slowly than expected.
- Red – Doubtful that any of the goals will be attained.

The DTO ratings are semi-quantitative metrics, reflecting the opinions of independent experts. The DTOs contain quantitative metrics, which provide a basis for determining progress of that effort towards a warfighter payoff.

3.4 BASIC RESEARCH (PROGRAM ELEMENT 0601384BP)

This program element (PE) funds the Joint Service core research program for CB defense (medical and non- medical). The basic research program aims to improve the operational performance of present and future DoD components by expanding knowledge in relevant fields for CB defense. Moreover, basic research supports a Joint Force concept of a lethal, integrated, supportable, highly mobile force with enhanced performance by the individual soldier, sailor, airman, or marine. Specifically, the program promotes theoretical and experimental research in the chemical, biological, medical, and related sciences. Research areas are determined and prioritized to meet Joint Service needs as stated in mission area analyses and Joint operations requirements, and to take advantage of scientific opportunities. Basic research is executed by academia, including Historically Black Colleges and Universities and Minority Institutions (HBCU/ MIs), and government research laboratories. Funds directed to these laboratories and research organizations capitalize on scientific talent, specialized and uniquely engineered facilities, and technological breakthroughs. The work in this program element is consistent with the *Joint Service Nuclear, Biological, and Chemical (NBC) Defense Research, Development, and Acquisition (RDA) Plan*. Basic research efforts lead to expeditious transition of the resulting knowledge and technology to the applied research (PE 0602384BP) and advanced technology development (PE 0603384BP) activities. This project also covers the conduct of basic research efforts in the areas of real- time sensing and diagnosis and immediate biological countermeasures. The projects in this PE include basic research efforts directed toward providing fundamental knowledge for the solution of military problems and therefore are correctly placed in Budget Activity 1.

3.4.1 CB Defense Basic Research (Project CB1)

This project funds basic research in chemistry, physics, mathematics, life sciences, and fundamental information in support of new and improved detection technologies for biological agents and toxins; new and improved detection technologies for chemical threat agents; advanced concepts in individual and collective protection; new concepts in decontamination; and information on the chemistry and toxicology of threat agents and related compounds.

3.4.1.1 CB1 Performance Goal (Outcome). The goal of the CB defense non-medical basic research program is to increase scientific understanding of the mechanisms and processes involved in the detection, protection against, and decontamination of chemical and biological warfare agents.

3.4.1.2 CB1 Outcome Measure

CB1 is minimally effective when	CB1 is successful when
• The results provide fundamental information in support of new and improved defensive systems, including information on – biosensors, – aerosol sciences, – chemistry and toxicology of bioactive compounds, – thin film technology development, – integrated detection of energetic and hazardous materials, – optical recognition technologies, – biological point detection, – protection, – decontamination,	• Information, technologies, or processes are transitioned to applied research or advanced technology development

CB1 is minimally effective when	CB1 is successful when
– simulants, – information technology • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	

3.4.1.3 CB1 Actual and Planned Performance

FY2002 Targets	Actual Performance
Biosensors - Sequence Venezuelan Equine Encephalitis (VEE) aptamers and incorporate all available aptamers into Multiplex Electronic/Photonic Sensor (MEPS). Conduct optimization and assess miniaturization potential of the capillary electrophoresis detection system and validate concept.	*Biological Detection* - Completed investigations of aptamer-based bio detection for anthrax strains; completed initial evaluations of Multiplex Electronic/Photonic Sensor (MEPS) technology. Initiated investigations of novel technologies to detect and identify BW simulants and agents in environmental matrices. Completed project to identify aerosol materials by analysis of scattering.
Chemistry and Toxicology of Bioactive Compounds - Construct "film badge" package to be used in the molecular imprinting technique for Individual Passive Chemical Agent Technologies and complete validation of concept for potential transition into 6.2 development. Conduct determination of rate laws for other organic oxidations using the new peroxide-based decontamination formulations. Complete development and validate filter model incorporating adsorption equilibria and dynamic behavior. Initiate a project to model filter performance concepts for individual protection systems. Expand pharmacokinetic and pharmacodynamic investigation to include additional new threat materials.	*Lightweight Chemical and Biological Sensors* - Completed the final phase of prototype testing of a sensor platform using Surface Acoustic Wave (SAW) and Semi-conducting Metal Oxides (SMO) devices for the detection of CW agents. Initiated a feasibility study to provide biological agent detection capability that may be combined with the chemical sensor. The technology is based on molecular imprinted polymers for biological materials. *Chemical Detection* - Completed investigation of dendrimer-based detection tickets; completed investigations of molecularly imprinting for chemical detection. Initiated efforts to detect CW agents using solid-state nano-arrays and analysis of degradation products.
New Detection Technologies – Initiate research on methods of combining chemical and biological agent detection on surfaces into one device. Include a variety of spectroscopic techniques focusing on portions of the electromagnetic spectrum not previously utilized for CB agent detection	
	Magnetic Resonance Spectrometer - Purchased a 900 MHz magnetic resonance spectrometer for the New York Structural Biology Center.
	Decontamination - Completed efforts to develop advanced decontamination materials to allow treatment of sensitive equipment, phase transfer materials, and solution chemistry. Initiated effort to develop decon materials for painted surfaces.
	Information Technology - Initiated effort to directly couple information into warning system by direct neural coupling.
	Protection - Completed investigations of rate and equilibrium properties of adsorbents for filtration modeling. Initiated investigations of self-assemblies for protective materials.
	Supporting Science - Initiated investigation of volatility and material interactions of CW agents and simulants under ambient environmental conditions.

3.4.1.4 CB1 Future Targets

FY 2003 Targets	FY 2004 Targets
Biological Detection - Continue investigations of novel technologies to rapidly and definitively detect and identify BW simulants and agents in environmental matrices. Initiate new effort based on light scattering approach.	*Biological Detection* - Continue investigations of novel technologies to rapidly and sensitively detect and identify BW simulants and agents in environmental matrices. Continue biodetection effort based on light scattering approach.
Chemical Detection - Continue efforts to detect CW agents using solid-state nano-arrays and analysis of degradation products.	*Chemical Detection* - Continue efforts to detect CW agents using solid-state nano-arrays and analysis of degradation products. Initiate effort to improve data analysis methods. Initiate efforts to assess novel technologies for chemical detection. Continue investigation of novel biological separation methods.
Decontamination - Complete investigations of environmentally benign decontamination materials based on peroxycarbonates; transition to development program. Initiate new efforts to develop advanced decontamination materials to allow treatment of sensitive equipment, phase transfer materials, and solution chemistry.	*Decontamination* - Continue effort to assess efficacy of novel gas phase decontaminate materials. Initiate new efforts to develop advanced decontamination materials and formulations.
Information Technology - Continue efforts to directly couple information into warning system by neural coupling.	*Information Technology* - Complete effort to directly couple information into warning system by neural coupling.
Protection - Continue investigations of self-assemblies for protective materials. Initiate effort to investigate agent interactions with microporous surfaces at the molecular level using Magic-Angle Spinning Nuclear Magnetic Resonance (MAS-NMR) spectrometry, Xray Photoelectron Spectroscopy (XPS), and thermal desorption methods.	*Protection* - Continue investigations of self-assemblies for protective materials. Continue effort to investigate agent interactions with microporous surfaces at the molecular level using Magic-Angle Spinning Nuclear Magnetic Resonance (MAS-NMR) spectrometry, Xray Photoelectron Spectroscopy (XPS), and thermal desorption methods.
Supporting Science - Continue investigations of the behavior of CW agents and simulants under ambient environmental conditions. Make available preliminary volatility and environmental adsorption data to Applied Research efforts for the Agent Fate program.	*Supporting Science* - Complete investigations of the behavior of CW agents and simulants under ambient environmental conditions. Make available preliminary volatility and environmental adsorption data to Applied Research efforts for the Agent Fate program.

3.4.1.5 Assessment of CB Defense Basic Research. Basic research efforts in FY2002 for project CB1 are effective. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects were initiated in FY2002. Some research efforts successfully transitioned to applied research. Congressionally directed programs were successfully executed during FY2002.

3.4.2 Medical Biological Defense Basic Research (Project TB1)

This project funds basic research on the development of vaccines and therapeutic drugs to provide effective medical defense against validated biological threat agents including bacteria, toxins, and viruses. This project also funds basic research employing biotechnology to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Categories for this project include current science and technology program areas in medical biological defense (diagnostic technologies, bacterial therapeutics, toxin therapeutics, viral therapeutics,

bacterial vaccines, toxin vaccines, and viral vaccines) and directed research efforts (anthrax studies and bug to drug identification and countermeasures program).

3.4.2.1 TB1 Performance Goal (Outcome). The goal of medical biological defense basic research is to increase scientific understanding of the mechanisms and processes involved in the pathogenesis of diseases caused by biological warfare (BW) agents, and the preventive, therapeutic, and diagnostic sciences underlying the technologies to counter these threats.

3.4.2.2 TB1 Outcome Measure

TB1 is minimally effective when	TB1 is successful when
• The results provide fundamental information in support of new and improved defensive systems, including information on – Bacterial Therapeutics, – Bacterial Vaccines, – Toxin Therapeutics, – Toxin Vaccines, – Viral Therapeutics, – Viral Vaccines, – Diagnostic Technologies, – Laboratory-based and Analytical Threat Assessment Research. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development

3.4.2.3 TB1 Actual and Planned Performance

FY2002 Targets	Actual Performance
Diagnostic Technologies - Continue investigating new medical diagnostic technologies based upon state-of-the-art biotechnological approaches for the enhanced recognition of infections by potential biological threats (bacteria, viruses, and toxins) of military interest.	*Diagnostic Technologies* - Continued investigating new diagnostic technologies based upon state-of-the-art biotechnological approaches for the enhanced recognition of infections by biological threats of military interest including new gene analysis chemistries and immunodiagnostics. Continued research to identify new biological markers and host responses for early recognition of infection including primer and probe sets against new gene targets. Continued to identify unique host immune markers using in vitro and in vivo models and developed primer and probe sets for these markers
Bacterial Therapeutics - Evaluate therapeutic indices for new (investigational) antibiotic agents identified by in vitro assays in suitable animal models. Study the effect of immunomodulators on the host response to B. mallei and Y. pestis candidate vaccines; identify those modulators that are effective in enhancing candidate vaccines.	*Bacterial Therapeutics* - Evaluated therapeutic indices for new (investigational) antibiotic agents identified by in vitro assays in mouse models. Studied the effect of immunomodulators on the host response to Burkholderia mallei (glanders) and Yersinia pestis (plague) candidate vaccines and identified modulators effective in enhancing candidate vaccines. Conducted studies on the effects of established therapeutic compounds on brucella in vitro.
Toxin Therapeutics - Refine and standardize in vivo screening models for assessment of efficacy of therapeutic intervention in botulinum toxin and SE intoxication and standardize in vitro assays for neutralizing activity of lead	*Toxin Therapeutics* - Developed high- throughput, cell- free screening assays for assessment of putative therapeutic inhibitors of several botulinum neurotoxin serotypes. Acquired and evaluated

FY2002 Targets	Actual Performance
inhibitors. Conduct high-output generation of candidate therapeutic moieties for botulinum and SE toxins using combinatorial chemistry. Evaluate inhibitor delivery strategies and demonstrate in vitro proof-of-concept. Begin high-throughput screening technology to investigate therapeutic candidates for exposure to ricin toxin.	extramural combinatorial libraries of compounds and natural extracts, as well as custom therapeutics as potential botulinum neurotoxin inhibitors. Obtained high- resolution crystal structures of selected inhibitors bound to botulinum neurotoxins. Continued development of cell- free screening models for assessment of staphylococcal enterotoxin (SE) therapeutics. Initiated high-throughput screening technology to investigate potential ricin therapeutics.
Viral Therapeutics - Determine the therapeutic potential of candidate drugs for treatment of disease for filovirus or orthopox infections. Characterize filovirus polymerases as potential antiviral drug targets and incorporate into in vitro assays.	*Viral Therapeutics* - Determined the therapeutic potential of candidate drugs for treatment of disease caused by filovirus or orthopox infections. Characterized filovirus polymerase as a potential antiviral drug target and initiated the development of in vitro assays incorporating filovirus polymerase to assess antiviral activity.
Bacterial Vaccines - Obtain genetic sequencing data from a panel of validated threat agents; establish genetic sequences into a database; evaluate sequence data for the potential for genetic engineering and genetic modification of the pathogens; determine genetic fingerprints (genetic identifiers) of various isolates of the organism responsible for plague (Y. pestis), glanders (B. mallei), and anthrax (B. anthracis). Evaluate genetically modified strains of Y. pestis, B. mallei, and B. anthracis for their level of virulence in animals. Identify genes from Y. pestis, B. mallei, and B. anthracis that encode for novel virulence factors. Expand and characterize strain collections of bacterial threat agents; identify strains of various agents that may be resistant to existing vaccines and/or those under advanced development.	*Bacterial Vaccines* - Obtained genetic sequencing data and established a database for Y. pestis, B. mallei, B. anthracis (anthrax), and Brucella spp.; evaluated data for potential for genetic engineering and genetic modification and determined genetic identifiers of various isolates of the organisms. Evaluated genetically modified strains of these pathogens for virulence in animals and identified genes that encode for novel virulence factors that may be new vaccine targets. Expanded and characterized strain collections of bacterial threat agents to identify strains that may be resistant to existing vaccines and/ or those under development. Characterized in vitro host cell gene expression during infection with plague, glanders, anthrax, and brucella and identified novel bacterial genes expressed. Tested multiagent vaccine constructs in avirulent anthrax and brucella platforms for immunogenicity in mice.
Toxin Vaccines - Complete experiments involving the crystallization of vaccine candidates for structural studies and biophysical characterization of vaccines and toxins. Complete assessment of novel adjuvants and delivery vehicles for aerosol-administered vaccines.	*Toxin Vaccines* - Completed experiments involving the crystallization of toxins and toxin vaccine candidates for structural studies and biophysical characterization. Assessed novel adjuvants and delivery vehicles for aerosol- administered vaccines. Investigated potential neutralizing epitopes in the translocation domains of botulinum neurotoxin serotypes.
Viral Vaccines - Continue investigating poxvirus immunity to determine if it is feasible to replace VIG with monoclonal antibodies and to construct a safe and effective vaccine to replace the vaccinia virus vaccine for variola.	*Viral Vaccines* - Continued investigating poxvirus immunity to determine the feasibility of replacing vaccinia immune globulin (VIG) with monoclonal antibodies and of constructing a safe and effective vaccine to replace the vaccinia virus vaccine for variola (smallpox).
Anthrax studies - Initiate development and testing of new approaches for the treatment of inhalational anthrax. Focus will be placed on two classes of compounds that inhibit the activity of the lethal toxin produced during anthrax infection and on a novel enzyme target, NAD synthetase, which is	*Anthrax studies* - Initiated development and testing of new approaches for the treatment of inhalational anthrax. Focused on two classes of compounds that inhibit the activity of the lethal toxin produced during anthrax infection and on an enzyme target,

FY2002 Targets	Actual Performance
critical for the germination and vegetative life cycle of *B. anthracis*	nicotinamide adenine dinucleotide synthetase (NADs), which is critical for the germination and vegetative life cycle of B. anthracis.
	Bug to Drug Identification and Countermeasures Program - Conducted research directed toward decreasing the time required to identify and counter biological threats. Focused on rapidly identifying host proteins altered by infection with biological threat pathogens and rapidly developing counter-measures based on how the countermeasures affect the host, outside of their desired effect against the pathogen. This research utilized structure- based small molecule design, microfluidics- based bioassays, and computational molecular biology and pathway modeling.

3.4.2.4 TB1 Future Targets

FY 2003 Targets	FY 2004 Targets
Diagnostic Technologies - Conduct basic research on new diagnostic approaches to the early recognition of infection; develop reagents and associated assays to aid in identifying new host and agent-specific biological markers that can be used for early recognition of infection. Continue research to develop, evaluate, and explore new technological approaches for diagnosis of potential biological warfare threat agents and for concentrating and processing clinical samples to support rapid identification and diagnostics.	*Diagnostic Technologies* - Continue basic research on new diagnostic approaches to the early recognition of infection focusing on technologies compatible with future comprehensive integrated diagnostic systems. Continue to develop reagents and assays for appropriate biological markers for early recognition of infection and identify new host and agent-specific biological markers. Continue research directed toward new technological approaches for diagnosis of biological threat agents and new sample processing technologies.
Therapeutics, Bacterial - Correlate metabolic measurements as a rapid and sensitive means to detect antibiotic activity with conventional susceptibility determinations and appropriate animal models of infection. Establish collaborative research and development agreements with pharmaceutical companies to test new and investigational antibiotics. Initiate evaluation of selected therapeutic compounds against Brucella.	*Therapeutics, Bacterial* - Evaluate novel lead antimicrobial compounds in small animal models for anthrax and plague. Initiate in vitro studies on the efficacy of established and investigational antibiotics against Francisella tularensis (tularemia).
Therapeutics, Toxin - Identify novel human and chimeric monoclonal antibodies by phage display methodology to aid in determining potential as botulinum neurotoxin therapeutics. Perform custom synthesis of lead compounds identified by high-throughput screening assays for botulinum neurotoxin and SE toxins. Co-crystallize toxin and lead therapeutics and collect x-ray diffraction datasets. Support development of combinatorial libraries and diversity sets for potential toxin therapeutics.	*Therapeutics, Toxin* - Continue custom synthesis of structural analogs of lead compounds identified by high-throughput screening assays for botulinum and SE toxins. Refine x-ray data for toxin-inhibitor co-crystal structures of most promising botulinum neurotoxin and SE inhibitors. Perform computational chemistry studies to refine lead compound co-crystal structures.
Therapeutics, Viral - Initiate development of intervention strategies for filovirus-induced shock and therapeutic approaches that combine antiviral and anti-shock drug therapy. Continue research for development of in vitro assays utilizing filovirus polymerase as a potential antiviral drug target.	*Therapeutics, Viral* - Continue research for development of intervention strategies for filovirus-induced shock and therapeutic approaches that combine antiviral and anti-shock drug therapy. Complete research for development of in vitro assays utilizing filovirus polymerase as a potential antiviral drug target.
Vaccines, Bacterial - Develop mutations in various	*Vaccines, Bacterial* - Continue studies on the molecular

FY 2003 Targets	FY 2004 Targets
biological agents for in vivo expressed genes to examine role in virulence. Characterize the mechanism(s) of vaccine resistance in selected strains of various biological agents. Determine mechanisms and correlates of protection with efficacious B. mallei vaccines. Evaluate differences in the course of brucella infection in different mouse strains. Test multiagent vaccine constructs for immunogenicity in animal models.	mechanisms of pathogenesis of plague, glanders, and anthrax. Identify additional virulence determinants of Brucella spp. Initiate a study to identify and characterize novel virulence proteins of F. tularensis.
Vaccines, Toxin - Compare the efficacy of constructs with neutralizing epitopes in other domains of botulinum neurotoxin serotypes with the current heavy chain (Hc) subunit toxin vaccine candidates.	*Vaccines, Toxin* - Conduct computational chemistry studies to develop next generation botulinum neurotoxin and recombinant ricin toxin A-chain (rRTA) vaccines. Evaluate theoretical feasibility of multivalent vaccines by protein engineering. Evaluate the role of glycosylation or other structural modifications in reducing efficacy of botulinum neurotoxin vaccines.
Vaccines, Viral - Complete investigating poxvirus immunity to determine the feasibility of replacing VIG with monoclonal antibodies and constructing a new vaccine to replace the vaccinia virus vaccine. Investigate the role of cytotoxic T cells in the Ebola virus-mouse model.	*Vaccines, Viral* - Complete investigating the role of cytotoxic T cells in the Ebola virus-mouse model. Initiate research to investigate the role of cytotoxic T cells in the filovirus model in higher animal species.
Anthrax studies - Continue extramural research efforts toward the development and testing of new approaches for the treatment of inhalational anthrax. Focus will continue on two classes of compounds that inhibit the activity of the lethal toxin produced during anthrax infection and on an enzyme target, NADs, which is critical for the germination and vegetative life cycle of B. anthracis.	

3.4.2.5 Assessment of Medical Biological Defense Basic Research. Basic research efforts in FY2002 for project TB1 are at least minimally effective. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2002. Successfully conducted research on Bug to Drug program to enhance development of new medical countermeasures.

3.4.3 Medical Chemical Defense Basic Research (Project TC1)

This project emphasizes understanding of the basic action mechanisms of nerve, blister (vesicating), blood, and respiratory agents. Basic studies are performed to delineate mechanisms and sites of action of identified and emerging chemical threats to generate required information for initial design and synthesis of medical countermeasures. In addition, these studies are further designed to maintain and extend a science base. Categories for this project include science and technology program areas (Pretreatments, Therapeutics, and Diagnostics) and directed research efforts (Low Level Chemical Warfare Agent Exposure and Fourth Generation Agents).

3.4.3.1 TC1 Performance Goal (Outcome). The goal of medical chemical defense basic research is to increase scientific understanding of the mechanisms, processes, and effects of

chemical warfare (CW) agents and the science involved in the detection, protection against, and decontamination of CW agents.

3.4.3.2 TC1 Outcome Measure

TC1 is minimally effective when	TC1 is successful when
• The results provide fundamental information in support of new and improved defensive systems, including information on – Toxicology of exposures to low levels of CW agents, – Pretreatments for chemical agent exposures, – Therapeutics for chemical agent exposures, – Non-traditional agents. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development

3.4.3.3 TC1 Actual and Planned Performance:

FY2002 Targets	Actual Performance
Pretreatments - Evaluate organophosphate anhydrolase for potential use as catalytic scavenger. Continue efforts to identify compounds for potential use as pretreatments for vesicant exposure. *Therapeutics* - Identify target sites for neuroprotection. Identify therapeutic targets for candidate compound combination therapies. *Low Level Chemical Warfare Agent Exposure* - Continue studies on identification of chronic pathological and behavioral effects of low level chemical warfare agent exposures. Investigate putative mechanisms of low level toxicity. Develop consensus for a coherent methodology for studies across endpoints and model species to permit integration of disparate endpoints, post-hoc analysis of research results, and extrapolation to nonhuman primate models. *Non-Traditional Agents* - Develop strategies to improve efficacy of current medical countermeasures against Non-Traditional Agents. Transition program to applied research	*Pretreatments* - Identified peptide for potential use as pre-treatment for vesicant exposure. Exploited new technology to develop recombinant biological scavengers. Initiated studies to investigate gene encoding serum carboxylesterase (CaE). *Therapeutics* - Identified through gene sampling target sites for neuroprotection. Identified therapeutic targets for candidate compound combination therapies. Initiated efforts to determine the optimal hypochlorite concentration for use in decontaminating chemical agent-exposed skin and agent-contaminated wounds. Determined the role of pro-inflammatory mediators derived from the release of arachidonic acid following sulfur mustard (HD) exposure. Studied biochemical mechanisms of HD toxicity and protection. *Diagnostics* - Investigated in vitro validation of sulfur mustard (HD)-induced proteases as biomarkers for exposure. *Low Level Chemical Warfare Agent Exposure* - Continued studies on identification of chronic pathological and behavioral effects of low level chemical warfare agent (CWA) exposures. Investigated putative mechanisms of low level toxicity. Developed consensus for a coherent methodology for studies across endpoints and model species to permit integration of disparate endpoints, post-hoc analysis of research results, and extrapolation to higher animal species. Examined alterations in muscle physiology produced by repetitive low-dose nerve agent exposures. Measured in vitro membrane electrical alterations caused by low concentrations of nerve agent. Investigated effects of acute and chronic exposure to low dose CWA on blood and brain cell apoptosis. *Non Traditional Agents* - Developed strategies to improve efficacy of current medical countermeasures against Non Traditional Agents (NTAs). Studied the effects of FGAs on energy metabolism in cardiac muscle cells.

3.4.3.4 TC1 Future Targets

FY 2003 Targets	FY 2004 Targets
Pretreatments - Target mechanism of vesicant injury and explore intervention of pro-inflammatory mediators and calcium modulators. Investigate efficacy of sulfur donors as anti-cyanide pretreatments. Develop animal model to test cyanide pretreatment compounds. Express and purify a recombinant human CaE for crystallization. Evaluate circulatory stability of recombinant bioscavengers. *Therapeutics* - Incorporate biomarker panels into screening modules. Evaluate combination therapies for neuroprotection efficacy. Evaluate antidotes representing new strategies to improve medical countermeasures against conventional and emerging agents. *Diagnostics* - Conduct electrophysiological analysis of CWAs in cultured cells. Analyze central nervous system (CNS) and peripheral protein production following soman exposure. Develop new assays for HD adducts in plasma and for diagnosing cyanide exposure. *Low Level Chemical Warfare Agent Exposure* - Continue studies on neurotoxic effects of low dose CWA exposure. Continue investigation of alterations in muscle physiology due to repetitive low dose CWA exposure. Characterize ultrastructural morphology, immunochemistry and gene expression following low level chemical exposure. Study the effects of low level chemical exposure on extracellular neurotransmitter levels. Evaluate organophosphate anhydrolase enzyme for potential use as a biomarker to confirm low level chemical exposure.	*Pretreatments* - Continue pretreatment intervention studies of vectors to deliver bioscavenger genes. Identify mechanism of action of vesicant pretreatment compounds. Evaluate cyanide toxicity using an inhalation model. Determine x-ray crystallographic structure of catalytic scavengers. Investigate efficacy of sulfur donors and methemoglobin formers as cyanide pretreatments. *Therapeutics* - Characterize animal models to test efficacy of nerve agent bioscavengers. Test physiologic pharmacokinetic model of CWAs. Determine effects of HD on cell structure using multiphoton laser scanning microscopy. Analyze in vitro effects of HD on cellular energy metabolism. Study in vitro biochemical changes induced by HD. Investigate enzymatic target of HD. Evaluate drug treatment strategies and combinations of therapies for nerve agent-induced seizures. *Diagnostics* - Identify molecular intracellular proteomic changes following HD exposure. *Low Level Chemical Warfare Agent Exposure* - Identify biomarker(s) to confirm low level chemical exposure and develop behavior assessment model. Identify potential medical countermeasures for low level chemical exposure.

3.4.3.5 Assessment of Chemical Biological Defense Basic Research. Basic research efforts in FY2002 for project TC1 are effective. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2002. Conducted research on diagnostics to enhance treatments of HD exposure.

3.5 APPLIED RESEARCH (PROGRAM ELEMENT 0602384BP)

The use of chemical and biological weapon systems in future conflicts is an increasing threat. Funding under this PE sustains a robust program, which reduces the danger of a chemical or biological attack and enables U. S. forces to survive and continue operations in a CB environment. The medical program focuses on development of vaccines, pretreatment, and therapeutic drugs, and on casualty diagnosis, patient decontamination, and medical management. In the non-medical area, the emphasis is on continuing improvements in CB defense materiel, including contamination avoidance, decontamination, and protection systems. This program also provides for conduct of applied research in the areas of real-time sensing and immediate biological countermeasures. The work in this PE is consistent with the *Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan*. Efforts under this PE transition to and

provide risk reduction for Advanced Technology Development (PE: 0603384BP), Advanced Component Development and Prototypes (PE: 0603884BP) and System Development and Demonstration (PE: 0604384BP). This project includes non- system specific development directed toward specific military needs and therefore is correctly placed in Budget Activity 2.

3.5.1 Chemical and Biological Defense Applied Research (Project CB2)

This project addresses the urgent need to provide all services with defensive materiel to protect individuals and groups from threat CB agents in the areas of detection, identification and warning, contamination avoidance via reconnaissance, individual and collective protection, and decontamination. The project provides for special investigations into CB defense technology to include CB threat agents, operational sciences, modeling, CB simulants, and nuclear, biological, chemical (NBC) survivability. This project focuses on horizontal integration of CB defensive technologies across the Joint Services. The Defense Technology Objectives (DTOs) provide a means to shape the development of selected technologies within this project.

3.5.1.1 CB2 Performance Goal (Outcome). The goal of the CB defense non-medical applied research program is to increase scientific understanding of the mechanisms and processes involved in chemical and biological warfare (CBW) agents and potential applications of this information for the development of advanced technologies for the detection, protection against, and decontamination of CBW agents.

3.5.1.2 CB2 Outcome Measure

CB2 is minimally effective when	CB2 is successful when
• The results provide fundamental information in support of new and improved defensive systems, including information on – biosensors for point detection and early warning, – critical reagents for biological agent detection & identification, – aerosol sciences, – threat agents, – agent dispersion and fate modeling, – advanced materials for individual protection, – advanced methods and materials for decontamination, – chemistry and toxicology of bioactive compounds, – man portable thin film technology, – integrated detection of energetic and hazardous materials, – optical recognition technologies, – new detection technologies. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs are rated GREEN by the TARA Panel.

3.5.1.3 Metric Description. The metric for CB2 is described in Section 3.2.1.1. Applied research also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annexes A–D of Volume I, *DoD Chemical and Biological Defense Program Annual Report to Congress.*

3.5.1.4 CB2 Actual and Planned Performance:

FY2002 Targets	Actual Performance
Biological Point Detection - Reduce size and logistic burden of optical fluorescence/shape analysis system and Py-GC-IMS sensors. Test against expanded set of biological simulants and interferents. Initiate exploration of new concepts for small, combined chemical and biological identifiers. Develop and test concepts toward automation of chip-based phylogenetic analysis of biological materials. Develop database of multiple gene targets for biological agents. Identify and initiate exploration of other concepts for multiplexed identification/ analysis of broad spectrum of biological agents. Continue generation and screening of recombinant antibodies against select biological agents, and transition best candidates to Critical Reagents Program. Initiate biological background data collection efforts to fill data gaps previously identified. *Collective Protection* - Determine TIC breakthrough and equilibrium data for advanced and novel adsorbents. Conduct prototype (large diameter bed) regenerative filter bed testing to demonstrate bed improvements and to update the performance model. Develop novel singlepass filter concepts using nanomaterials and identify absorbents to support that concept. Evaluate shelter materiel using technologies identified to facilitate rapid development of an improved product. *Modeling and Simulation of Joint Operability* - Expand model development for simulation of CBW effects on joint force operations for incorporation into advanced simulations. Demonstrate operational capability of the STAFFS model for simulation of CBW effects on operations at APODs and SPODs. *Modeling and Simulation of CBW Environment* - Expand development of advanced CB weapons models (Lagrangian particle and complex fluid dynamics methodologies) for more accurate, higher-resolution atmospheric transport and fate predictions in complex and urban terrain for battlespace awareness and contamination avoidance. Extend development of high-altitude CB agent behavior for application in Tactical Ballistic Missile (TBM) intercept analysis. Begin development of the capability to accurately model the interaction (evaporation and persistence) of chemical	*Advanced Adsorbents for Protection Applications (DTO-CB08)* - Developed an improved/modified ASZM-TEDA adsorbent that enhances protection against ammonia and formaldehyde. Identified adsorbent bed compositions that provided reduced JSGPM/JSAM encumbrance (pressure drop; weight; size). Evaluated chemical removal performance of ASZM-TEDA adsorbent and approximately 500 other novel adsorbent materials against design limiting TICs. Developed initial concept compositions and transitioned novel adsorbents for removal of Toxic Industrial Chemicals (TICs) for incorporation into the JSGPM. *Enzymatic Decontamination (DTO-CB09*) - Completed characterization of H-agent enzymes. Conducted initial efficacy testing of a combined enzyme formulation. *Chemical Imaging Sensor (DTO-CB19)* - Demonstrated a 16-pixel spectrometer operating at 360 Hz with off-line processing of data. *Biological Sample Preparation System (BSPS) for Biological Identification (DTO-CB20)* - Initiated testing of a new series of taggant chemistry for multi-agent, multiplexing Polymerized Chain Reaction (PCR) assays to reduce overall number of needed assays. Initiated redesign of fluidic systems from PCR breadboard to reduce processing time, target is 20 minutes for sample processing. *Standoff Biological Aerosol Detection (DTO-CB35)* - Established system requirements and conducted down selection based on weighted criteria. Established technical potential of top ranked technologies. Performed testing, analyzed data, and identified strengths and weaknesses on the top five rated technologies for the next generation standoff system. *End-of-Service-Life Indicator for NBC Mask Filters (DTO-CB36)* - Completed initial baseline data characterization of the performance of the most promising ESLI technologies. Completed assessment of performance parameters of initial candidate technologies including reaction time, range of detection, and effects of temperature and humidity using carbon bed test cells. *Detection of Agent in Water* - Completed construction of initial breadboard component candidates. Completed testing of component candidates to identify shortfalls. Initiated technology assessment. *Environmental Fate of Agents (DTO-CB42)* - Initiated literature survey of reports relevant to the fate of chemical agents deposited onto surfaces have been captured, reviewed and rated. Data from wind tunnel tests and field trials detailed in reviewed documents has been extracted and added to a surface evaporation database that can be used for model development, calibration, and validation. Completed a parameter sensitivity analysis using existing modeling capability, which will better focus agent fate laboratory studies. Wind tunnels and outdoor facilities were completed in the US and UK which allows testing using live chemical agents. *Chemical and Biological Warfare Effects on Operations (DTO-CB43)* - Tested and demonstrated fighter base representation. Expanded development of Aerial Port of Debarkation (APOD)

FY2002 Targets	Actual Performance
agents with materials and the reaerosolization of biological agents. *Supporting Science and Technology* - Continue assessment of gaps in threat agent data, and identify needs for improved simulants in CB defense materiel development. Initiate a program of synthesis, toxicology screening, and characterization of new threat materials (to include NTAs) identified as urgent needs while continuing assessment of long-term needs. Initiate development of improved simulants for chemical aerosols, microencapsulated viruses, stabilized bacteria, and proteinaceous and nonproteinaceous toxins/ bioregulators. Continue to measure quantitative performance of candidate aerosol collectors for advanced point biological detection technology. Initiate the design of a new generation of aerosol concentrators and collectors using micromachining technology to reduce size, power consumption, and weight, in order to meet stringent requirements for advanced miniature detection systems. Initiate design of advanced aerosol inlets to meet Joint Service requirements for high collection efficiency over the respirable particle size range at wind speeds up to 60 mph. Continue to provide controlled biological simulant aerosol challenges for Joint Service, DARPA, and DOE experimental equipment in preparation for the JFT. Assemble a database on agent fate on surfaces incorporating prior year's findings. Complete BW reaerosolization studies. *Detection of Contaminants on Surfaces* - Initiate a program to develop technology to detect the presence of CBW contaminants on surfaces, for use in vehicular and handheld systems. Initial studies will focus on active and passive optical technologies that could be employed on or from a vehicular platform. *Chemical Point Detection* - Test/demonstrate the capabilities of the high potential alternative technologies from the technical evaluation of technology conducted in FY01 for the JCBAWM effort. *Modeling and Simulation of CB Defense Equipment* - Expand development of models for Joint Service CB defense equipment for application in Simulation Based Acquisition (SBA) training, distributed simulations, wargaming, and military-worth evaluations.	methodology. Began data gathering and development of Sea Port of Debarkation (SPOD) module. Continued model infrastructure development and detailed operations effects (work/rest cycle, shift change, MOPP, dewarn, etc.). *Oxidative Decontamination Formulation (DTO-CB44)* - Optimized oxidative formulations using a peroxycarbonate-based approach and began kinetics, toxicity, and material compatibility testing. Developed several candidate formulations and evaluated commercial catalysts to improve oxidation rates for a peracid-based decontaminant. *Self-Detoxifying Materials for Clothing Applications (DTO-CB45)* - Completed initial assessment of enzymes, polyoxometalates, and cyclodextrins for their incorporation into nanofibers for agent deactivation. Completed initial selection of reactive nanoparticle candidates for incorporation into films and fibers for improved barrier protection. Completed development of a process to bind N-halamines to target clothing material, and completed initial testing to characterize and quantify the reactivity of treated materials. *Bioinformatics* - Adapted bioinformatic approaches developed for the human genome project to produce meaningful generalizations about the large number of candidates that can be potentially used for biological threat agents and their varied or engineered properties. Initiated integrating comprehensive and interactive databases maintained and updated with fundamental properties of biological agents of military interest. Initiated development of data mining tools to analyze microbial information specifically tailored to military assessment and decision making for CB defense. Initiated the development of predictive algorithms embedded into databases developed above to understand biological threats, allow generalizations, assess risk of emerging biological threats, and suggest the course of defense response under specific circumstances (e.g., pathogenic genes in unnatural host context, or potential threat of engineered genomes). *Air Purification Systems* - Developed methodology for testing anti-microbial filters/treatments for collective and individual protection. Established R&D contract for reactive filter media. Initiated design of test apparatus to challenge reactive media with biological aerosol simulants. Conducted modeling and testing of lab- and sub-scale anti-microbial air purification devices, which have potential to enhance bio-safety and reduce operating costs associated with air purification. *Joint Biological and Chemical Terrorism Response Project* - Completed development of rapid anthrax test method for blood and environmental samples initiated in CB Countermeasures. Initiated development of rapid test for smallpox and plague. Completed revision of medical training and reference for treatment of chemical and biological exposures for non-military hospitals. Continued development and initial testing of the wide area biological counter-terrorism surveillance and detection tool. Developed protocols for safe transport of biologically contaminated clinical samples. Continued development and initial testing of a transportable fiber optic detector for a wide variety of biological threat agents found in the

FY2002 Targets	Actual Performance
Early Warning Detection - Demonstrate concept and technology of a test representtative RADAR system for queuing of stand off systems. Investigate options for linking disparate sensors to battlespace management systems. *Individual Protection* - Incorporate aerosol threat mediation techniques in the fabrication of concept garments. Initiate testing of concept garments. Identify and incorporate color transition materials into nano-fiber membranes and test for response to agent simulants. Evaluate fielded and developmental clothing materials for the protection they provide against TICs. Produce trial membranes using ion implantation techniques, and evaluate their material physical properties and agent protection capabilities. Conduct a study of adsorbent fabric placement in semi-permeable membrane garments for added vapor and aerosol protection. Fabricate and evaluate a proof of concept model of the helmet/mask concept using the parametric skeleton model. Construct and evaluate prototype mask end of service life indicators. Initiate development of advanced concepts in mask air filtration/purification. *Decontamination* - Continue developmental efforts to address JSSED Block II and III approaches focusing on thermal technology and spot cleaning methodology. Develop solution approaches for Superior Decontamination Systems combining novel chemical and biochemical technologies into a unified approach. Complete the evaluation determining the physical limitations of novel solid technology and implement findings into the program. Determine best future uses for these materials *Low Level Chemical Agent Operational Studies* - Complete miosis threshold studies for sarin over extended exposure durations. Continue G agent potency ratio studies on rats. Initiate multi-species animal studies for G agents. Initiate planning for nerve agents studies in rats. Initiate physiological modeling efforts to understand the dependence of toxicological effects on the route of exposure to low level nerve agents. *FGA (non-medical)* - Modify point detection systems to enhance performance against new chemical targets and characterize effect of	field. Continued research into identification of the genetic factors affecting bioterrorism toxicants and toxins. Continued practical recommendations for hospital hygiene practices dealing with bioterrorism. Completed the initial selection of biological and chemical isolation suits for bioterrorism response. *Common Asset for Biological Security* - Developed genome based bioinformatics tools, assessed performance, and applied to gene chip detection/identification technologies. *CB Countermeasures* - Continued investigations into mechanisms of cell death after exposure to chemical and biological agents. Developed and initiated testing of new, non-woven protective suits for response to chemical and biological threats. Continued investtigations into feasibility of employing selenium bound receptors to destroy and eliminate infectious biological agents. Continued development of embedded miniature chemical detectors for employment in critical and sensitive sites. *Integrated Detection of Energetic and Hazardous Materials* - Developed arrays of Cylindrical Ion Traps Mass Spectrometers and the methodologies to analyze the spectra in parallel. Investigated the Ion Trap Mass Spectrometer (ITMS) methodologies for the point detection of BW agents. Tested the limits of detection via neutron initiated gamma-ray spectroscopy and compare to the theoretical results. Investigated application of advanced transforms on multi-sensor detection models. *CB Regenerative Air Filtration System* - Constructed a facility for toxic and chemical agent testing on one-half scale regenerative pressure/temperature swing adsorption (P/TSA) air filtration devices. A UK manufacturer supplied a prototype filtration unit. Initiated testing on this unit to identify the performance limits and develop concepts for an optimized design. *CB Point Detection, Biological Identification* - Continued development of Force Discrimination Assay. Continued development of concepts for automation and initiated testing of chip-based phylogenetic analysis of biological materials. Initiated feasibility study to determine technological issues associated with microwave spectroscopy of biological materials under ambient conditions. Initiated exploration into non-Taqman chemistry for PCR. Initiated evaluation of quantum dot technology for application to enhance antibody ticket technology for improved stability and sensitivity. Identified combinatorial peptides as potential simulants for biological agents. *CB Point Detection* - Initiated modification of point detection systems to enhance performance against new chemical targets. Initiated assessment of modifications on system impacts to power usage, reliability, and overall system life expectancy. Broadened spectral knowledge base in order to predict performance of active and passive IR sensors for detection of surface contamination. Initiated evaluation of novel materials and material treatment solutions to decrease penetration of aerosol particulates through overgarments. *CB Point Detection, Integrated CB Detection* - Initiated characterization of biomarkers observed in Py-GC-IMS sensors

FY2002 Targets	Actual Performance
modifications on performance to existing chemical targets and on interference rejection. Broaden spectral knowledge base in order to predict performance of active and passive IR sensors for detection of surface contamination. Examine novel materials and material treatment solutions to decrease penetration of aerosol particulates through overgarments. *Biological Standoff* - Investigate novel approaches to detection and discrimination of biological aerosols in standoff mode. Examine application of improved laser sources and methodologies and develop spectral database and methodologies to support assessment of new approaches such as Brillouin scattering, Mueller matrix LIDAR, millimeter wave spectroscopy. Investigate potential applicability of UV and IR imaging. *Agent Fate* - Identify standard construction and natural environmental materials and study interactions of these materials with chemical agents using novel in situ methods. Develop refined laboratory methodologies to support these studies. Define previously unaccounted environmental loss mechanisms and provide results for improvement of hazard modeling. Refine relevant physical property data relate to chemical hazard evolution. *CB Modeling/Simulation* - Enhance spatial resolution of hazard prediction codes through physical models that incorporate resolution improvements in radiation, turbulence, and precipitation physics. Initiate coupling of numerical weather prediction models with existing CBW dispersion codes.	against performance matrix of sensitivity, selectivity, and interference rejection for optimal design trade-off analysis. Initiated evaluation and development of novel concepts, methodologies, and techniques for biological discrimination, advanced aerosol handling, and triggering capabilities for chemical aerosols. *CB Standoff Detection, Biological Standoff* - Investigated new and novel methods for detecting biological aerosols. Technologies included Brillouin spectroscopy, passive interferometry, and polarized light scattering. *CB Standoff Detection, Chemical Standoff* - Collected quantitative vapor and diffuse reflectance data on chemical simulants. *CB Standoff Detection, Integrated CB Detection* - Initiated a program to develop technology to detect the presence of CBW contaminants on surfaces for use in vehicular and handheld systems. Initial studies focused on active and passive optical technologies that could be employed on or from a vehicular platform. Conducted assessment of standoff technologies that may be implemented simultaneously against chemical and biological agents. Initiated a program to develop a wide agent spectral range technology to detect the presence of CBW vapors, aerosols, and rains. Conducted assessment of standoff technologies that may be implemented simultaneously against chemical and biological agents. *Collective Protection, Filtration* - Completed single pass filtration model validation and evaluated candidate adsorbents against high priority TICs and for use in regenerative filtration applications. Demonstrated single pass filter concepts using nano-materials. Initiated proof-of-principle testing and evaluation of 50 CFM pressure-temperature swing adsorption filter to validate model. Evaluated and identified best performing candidate adsorbents for use in regenerative filtration (P/TSA) applications. Initiated evaluation of electrostatic filter particulate and aerosol capture enhancement and degradation effects of TICs on HEPA filters and ways to mitigate. Initiated trade study assessment on the feasibility and application of open and closed circuit air supply and rebreather technologies. Developed Residual Life Indicators (RLI) test beds. Continued chemical sensor RLI testing and started physical sensor testing. *Collective Protection, Shelters* - Completed Collective Protection Front End Analysis and Master Plan. Continued development and evaluation of advanced CB shelter materials (shell, support, airlocks, liner, seams, and seals). Developed new CB skin material, identified and evaluated commercial waterproof zippers, developed and designed prototype linear track profiles, assessed four hermetic sealing methodologies for current set of shelter materials. Initiated development and assessment of chemistries for self-decontaminating shelter materials. Provided initial assessment of failure mechanisms of shelter materials to conventional weapons blast pressure effects. *Decontamination, Sensitive Equipment* - Continued developmental efforts to address Joint Service Sensitive Equipment Decon Program (JSSED) Block II and III approaches focusing on plasma technology and spot cleaning methodology using emerging solvents

FY2002 Targets	Actual Performance
	and solid/solvent suspensions. *Decontamination, Solid Phase Chemistry* - Evaluated the physical limitations of novel solid phase technology for decontamination operations. Efforts focused on nanoscale metal oxides and zeolites. Implemented these findings into other areas of the decon program and determined the best future uses for these materials. *Decontamination, Solution Chemistry* - Completed a feasibility study examining the potential to combine multiple developmental solution chemistry approaches into single formulations. Initiated live agent screening using dioxiranes. Optimized enzymes effective against GV and other organophosphorous agents. *Individual Protection, Clothing* - Completed optimization of aerosol threat material (nanofiber web) and processes resulting in a more durable fabric system. Completed initial testing of fielded and developmental protective garment materials to evaluate their effectiveness against TICs. Completed laboratory trials to enhance the permselectivity of membranes by ion implantation, and characterized the material physical properties and CB agent protection capabilities of those trial membranes. Completed a Dual Use Science and Technology (DUST) effort to demonstrate the large scale production of protective membrane-based garments for military and civilian applications and submitted candidates to the JSLIST Alternate Source Qualification program for consideration. Completed identification of the most promising permselective membrane candidates and initiated the characterization of those candidates. Completed initial investigations of novel materials and material treatment solutions to decrease penetration of non-traditional threat agents (NTA) aerosols through overgarments. *Individual Protection, Masks* - Completed concept studies for the long-term integrated mask/helmet. Completed preliminary technology feasibility studies for advanced mask concepts. Completed comparison of existing filtration media with reactive iodine media with respect to physical properties (such as pressure drop and dust/particulate removal), and transitioned further development to the Air Purification Systems project. Completed initial screening of candidate sorbent media structures to evaluate their critical properties, and identified the three best candidates for further development. Completed initial screening of candidate advanced lens materials to evaluate their critical properties and down-selected to three materials for further development. Completed survey of available technologies that can be used for assessing mask characteristics critical for improved protection, flow dynamics, heat and moisture transfer, and fogging. *Information Systems Technology (IST), CB Battle Management* - Initiated Battle Management Front End Analysis to identify optimum investment strategy. Completed analysis/report on tests of non-CB sensors against CB stimulant disseminations. Expanded database on non-CB sensor performance through measurement against additional dissemination approaches. Conducted studies to assess value added through data fusion of networked multiple same-type disparate sensors and multiple different disparate sensors.

FY2002 Targets	Actual Performance
	IST, CB Environment - Completed methodology documentation and validation of VLSTRACK. Increased computational speed and concentration fluctuation representation in next-generation hazard evolution model (MESO) with concurrent validation. Improved high resolution computational fluid dynamics model (CBW-CFX) to address realistic droplet size distributions and biological agent decay. Initiated coupling of numerical weather prediction models with existing CBW dispersion codes. Initiated refinement of hazard evolution codes to better incorporate effects of the environment on chemical agents. *IST, CB Planning, Training and Analysis* - Initiated simulation hazard modeling for systems and forces via distributed simulations systems. Initiated examination of sensitivity of hazard evolution/prediction models for agent toxicity. *IST, CB Simulation Based Acquisition* - Developed plan for highest priority prototyping demonstrations. Initiated coupling of CBD commodity area object models with demonstrated prototyping system. Initiated definition of performance and technical specifications of an eventual virtual prototype system (VPS) to improve acquisition process of CBD materiel. *Supporting Science and Technology (SS&T), Aerosol Technology* - Measured quantitative performance of six candidate aerosol collectors for advanced point biological detection technology. Initiated design of advanced aerosol inlets to meet Joint Service requirements for high collection efficiency over the respirable particle size range at wind speeds up to 60 mph. Initiated the design of a new generation of aerosol concentrators using mini-machining technology to reduce size, power consumption, and weight, in order to meet stringent requirements for advanced detection systems. Continued to provide controlled biological simulant aerosol challenges for Joint Service, DARPA, and DOE experimental equipment in preparation for the Joint Field Trials (JFT). *SS&T, Threat Agents* - Continued assessment of gaps in threat agent data, and identified requirements for improved simulants in CB defense materiel development. Initiated a program of synthesis, toxicology screening, and characterization of new threat materials (to include persistence properties of novel agents) identified as urgent needs while continuing assessment of long-term needs. Initiated validation studies on simulant BG spores, improvement of simulant Erwinia herbicola, and selection of new simulants for novel chemical agent aerosols. Initiated research on persistence of bacteria and spores. Initiated establishment of an agent/simulant knowledge base technical information system. *Low Level Operational Toxicology* - Completed miosis threshold studies for second generation agents in rats over extended exposure durations. Completed GF and GB potency ratio studies on rats. Initiated non-rodent animal studies on G agents to support the extrapolation of data to humans. Developed methodology for VX inhalation studies to characterize Ct relationships for low level longer duration exposures. Developed CWA tissue dose metric to quantify exposure and predict toxicological response.

3.5.1.5 CB2 Future Targets

FY 2003 Targets	FY 2004 Targets
Advanced Adsorbents for Protection Applications (DTO-CB08) - Identify at least one adsorbent bed composition that provides the level of protection required by the JSGPM and JCPE programs for all CW agents and the highest priority TICs. Develop at least one adsorbent bed composition providing for effective P/TSA system performance (meeting JCPE requirements) for all chemical warfare agents and all high priority TICs. *Biological Sample Preparation System (BSPS) for Biological Identification (DTO-CB20)* - Continue develop of new taggant chemistry for multi-agent, multiplexing PCR assays. Complete redesign and initiate modifications to the breadboard. *Standoff Biological Aerosol Detection (DTO-CB35)* - Initiate construction of breadboard biological standoff detection system based on the results of the downselect, user input, and prior year testing. *End-of-Service-Life Indicators for NBC Mask Filters (DTO-CB36)* - Complete baseline evaluations of candidate technologies. Downselect best candidate technologies. Fabricate and evaluate ESLI/filter concept models. Optimize baseline design and determine optimum ESLI location. *Detection of Agent in Water* - Complete technology assessment transition to Advanced Technology Development. *Environmental Fate of Agents (DTO-CB42)* - Complete literature survey effort which will review and rate documents from a very large survey done by Battelle for DTRA. Surface evaporation data will be extracted from this and added to the data base. Laboratory studies will focus on processes affecting VX deposited onto concrete, both on and within the substrate, so that detailed modeling can be done to accurately predict the associated contact and inhalation hazards. The same agent-substrate baseline tests will be done at multiple locations to result in the first correlation of agent fate behavior between wind tunnels and outdoor facilities. The rate of absorption of thickened chemical agents on concrete and subsequent desorption will be measured to provide crucial data needed for better CONOPS for fixed sites. *Chemical and Biological Warfare Effects on Operations (DTO-CB43)* - Complete and demonstrate initial operational capability of APOD module. Conduct independent Validation and Verification (V&V) of fighter base module. Initiate development and testing of Sea Port of Debarkation (SPOD) module. *Oxidative Decontamination Formulation (DTO-CB44)* - Conduct contact hazard and off-gas testing on coupons	*Advanced Adsorbents for Protection Applications (DTO-CB08)* - Complete Performance Verification of Adsorbents for Use in NBC Filtration Systems - Selected adsorbent beds will undergo performance verification testing to fully assess the performance constraints expected in the host filter system. These evaluations will consider adsorbent bed performance under a wide range of agent challenge concentration scenarios and environmental conditions. *Biological Sample Preparation System (BSPS) for Biological Identification (DTO-CB20)* - Complete and demonstrate new taggant chemistry for multi-agent, multiplexing PCR assays. Complete and demonstrate modifications to the breadboard system for 20 minute sample processing. *Standoff Biological Aerosol Detection (DTO-CB35)* - Complete construction of breadboard biological standoff detection systems. Test systems and prepare for transition. *End-of-Service-Life Indicators for NBC Mask Filters (DTO-CB36)* - Fabricate and evaluate first-generation ESLI prototype demonstrator units against the target agents and select TICs to validate achievement of performance goals. The evaluation will include environmental testing to assess the effects of temperature and humidity extremes, long-term storage, and rough handling on ESLI performance. *Environmental Fate of Agents (DTO-CB42)* - Behavior of current threat agents in both neat and thickened forms will be studied at the bench scale, in wind tunnels, and with field trials in well coordinated tests to provide data necessary for model development and refinement for asphalt and live grass. Contact hazard of chemical agents on fixed site surfaces will be studied to provide data sufficient for model development and refinement. *Chemical and Biological Warfare Effects on Operations (DTO-CB43)* - Investigate feasibility of extending fixed-site operational modeling methodology to include mobile forces. Conduct independent V&V on core model and transition Sea Port of Debarkation (SPOD) operational effects model to JOEF. *Oxidative Decontamination Formulation (DTO-CB44)* - Initiate chamber testing over operational temperature range, finish material compatibility testing, and formulate peroxycarbonate and peracid candidates into a dry powder and/or concentrated liquid. Finalize formulation of newly added oxidative approaches and conduct material compatibility and agent testing. *Self-Detoxifying Materials for Clothing Applications (DTO-CB45)* - Evaluate durability of carbon-loaded melt

FY 2003 Targets	FY 2004 Targets
and continue material compatibility testing for the peroxycarbonate approach. Optimize formulations using the peracid approach and conduct live agent testing with candidate formulations. Integrate other oxidative approaches into the DTO. *Self-Detoxifying Materials for Clothing Applications (DTO-CB45)* - Continue to assess new reactive compounds and treatments for improved detoxification in membranes. Develop concepts for nanoreactors and surface-migrating phases for improved agent breakdown within membranes and coatings. Select relevant reactive nanoparticles and polymeric materials for subsequent processing and testing studies. Characterize the reaction kinetics and loading capacity of N-halamines treated materials with CWA simulants. *CB Point Detection, Biological Identification* - Complete development of Force Discrimination Assay (FDA). Continue development and testing automation of chip-based phylogenetic analysis of biological materials. Complete feasibility study to determine technological issues associated with microwave spectroscopy of biological materials under ambient conditions. Continue development of non-Taqman chemistry for PCR. Laboratory demonstrate quantum dot technology for application to enhance antibody ticket technology for improved stability and sensitivity. *CB Point Detection, Integrated CB* - Initiate exploration of new concepts for small, combined chemical and biological identifiers. Initiate feasibility studies of "low consumable or reagentless" concepts. Develop and test the redesigned Py-GC-IMS hardware and software for improved chemical and biological discrimination. Continue evaluation and development of novel concepts, methodologies, and techniques for biological discrimination, advanced aerosol handling, and triggering capabilities for chemical aerosols. *CB Standoff Detection, Biological Standoff* - Initiate program for the collection of spectral data of biological aerosols. Collect quantitative scattering and absorption spectra on biological simulant aerosols. *CB Standoff Detection, Chemical Standoff* - Initiate construction of hyperspectral sensor in preparation for airborne sensor demonstration. *CB Standoff Detection, Integrated CB Detection* - Initiate construction of wide agent spectrum detection system based on downselect. *Collective Protection, Filtration* - Complete proof-of-principle testing and evaluation of 50 CFM pressure-temperature swing adsorption filter to validate model. Initiate 200 CFM pressure-temperature swing adsorption filter to assess scalable model and applicability for	blown/electrospun liners; measure breakthrough, speed and extent of reaction of agent simulants in scaled up membranes; develop adhesive bonding methodology for elastic detoxifying membrane adhesion to woven and knit fabrics; develop fabric/clothing design to maximize reactive treatments. Prepare and evaluate polymeric films, fibers, and/or permselective membranes with incorporated reactive nanoparticles of selected types and different loading levels. Treat full garments with N-halamines and other oxidative compounds and assess the physical and chemical characteristics of those garments. *CB Point Detection, Biological Identification* - Complete exploration and testing automation of chip-based phylogenetic analysis of biological materials. Initiate design and build of breadboard system using technology based on microwave spectroscopy of biological materials under ambient conditions. Complete and demonstrate non-Taqman chemistry for PCR assays. Identify system development and demonstration issues for the transition of quantum dot technology to the Critical Reagent Program for application to enhance antibody ticket technology for improved stability and sensitivity. *CB Point Detection, Integrated CB Point Detection* - Continue exploration of new concepts for small, combined chemical and biological identifiers. Continue feasibility studies of "low consumable or reagentless" concepts. Complete testing, demonstrate, and transition to Advanced Technology Development the redesigned Py-GC-IMS hardware and software for improved chemical and biological discrimination. Complete evaluation, downselect technology for a system design, and continue development of novel concepts, methodologies, and techniques for biological discrimination, advanced aerosol handling, and triggering capabilities for chemical aerosols. *CB Standoff Detection, Biological Standoff* - Extend spectral data base work to include live agents. *CB Standoff Detection, Chemical Standoff* - Complete construction of hyperspectral sensor. Integrate sensor into helicopter and conduct airborne demonstration against chemical agent vapor simulant. *CB Standoff Detection, Integrated CB Detection* - Complete construction on wide agent spectrum detection system and conduct initial lab testing against CB simulants. *Collective Protection, Filtration* - Characterize constraints of mature candidate adsorbent compositions, including aging, cyclic flow capacity, relative humidity, temperature and material compatibility. Assess chemical removal performance of prototype JSGPM filters containing adsorbent developed under DTO-CB36.

FY 2003 Targets	FY 2004 Targets
advanced system integration. Optimize candidate adsorbents for use in regenerative filtration (PSA/TSA) applications that are effective against a wide spectrum of TIC and Chemical Warfare Agents (CWA). Complete evaluation of electrostatic filter particulate and aerosol capture enhancement and degradation effects of TICs on HEPA filters and ways to mitigate. Finish trade study assessing feasibility and application of open and closed circuit air supply and rebreather technologies. Complete chemical and physical Residual Life Indicators sensor testing. *Collective Protection, Shelters* - Continue development and evaluation of advanced CB shelter materials (shell, support, airlocks, liner, seams, and seals). Testing of new CB skin material including constructed shelter systems. Continued development and testing of chemistries for self-decontaminating shelter materials. Complete initial assessment and modeling of shelter materials failure mechanisms to conventional weapons blast pressure effects and transition to JCPE. *Decontamination, Sensitive Equipment* - Initiated feasibility studies for decontamination technology solutions for JSSED Block II and III using plasma technology and spot cleaning methodology using reactive solid/solvent suspensions. *Decontamination, Solid Phase Chemistry* - Develop and demonstrate novel solid and sorbent decontamination applications using nanoscale metal oxides, solvents, and reactive additives. *Decontamination, Solution Chemistry* - Optimize formulations for chemical and biological decontamination systems. Initiate material compatibility and efficacy testing on an expanded test bed for promising approaches. Optimize an innovative catalytic buffering system to provide pH control in solution decon formulations. Complete final kinetics and panels testing for the combined enzyme decontamination system. *Individual Protection, Clothing* - Complete testing of fielded and developmental protective garment materials to evaluate their effectiveness against TICs, and provide recommendations to the user community. Develop and produce a first generation membrane that has optimized permselectivity through ion implantation. Complete transport and physical characterization of selected candidates, and initiate detailed analysis of structure-property relationships. Optimize materials and material treatment solutions for overgarments to improve protection against NTA aerosols. Initiate a study to assess the effects of atmospheric temperature and wind on agent penetration of Individual Protection Equipment (IPE). Validate recent research that indicates that intermittent cooling to various body regions can provide	Characterize constraints of mature candidate adsorbent compositions against a wide range of TIC and CWA including, aging, chemical reaction, regeneration cycles, relative humidity, temperature and material compatibility. Optimize regenerative process (including, temperature, pressure, ECS, cycle time) using verified candidate adsorbent materials. This task will mature the technology for future consideration as an advanced technology demonstrator. *Collective Protection, Shelters* - Continued development and testing of advanced CB shelter materials (shell, support, airlocks, liner, seams, and seals) and constructed shelter systems. Identify and test optimal chemistries for self-decontaminating shelter materials and applications. *Decontamination, Sensitive Equipment* - Complete plasma technology demonstration for applications in JSSED Blocks II/III. *Decontamination, Solid Phase Chemistry* - Conduct materials compatibility studies and coupon validation studies on promising solid phase efforts identified in FY02-03. *Individual Protection, Masks* - Refine advanced mask system concepts using actual technologies to the maximum extent possible. Optimize candidate mask technologies to enhance protection, flow dynamics, heat and moisture transfer, and fogging. *IST, CB Battle Management* - Continue development of methods to improve real-time, network-aided decision making, and visualization of network responses. *IST, CB Environment* - Continue improvements of the next-generation model (MESO) and demonstrate maturity for transition to JEM Block 2. Continue development of computational fluid dynamics model (CBW-CFX) and identify areas for improvement. Validate performance of coupled weather CBW dispersion model. Complete evaluation of performance of hazard evolution codes updated by agent environmental effects data. *IST, CB Planning, Training and Analysis* - Transition distributed simulation application of hazard models to Joint Operational Effects Federation and NBC Training & Capability Simulation (TCS). *IST, CB Simulation Based Acquisition* - Continue development and improvement of potential candidate technologies for inclusion in a Virtual Prototype System (VPS). *SS&T, Aerosol Technology* - Continue to measure quantitative performance of candidate aerosol collectors for advanced point biological and chemical detection

FY 2003 Targets	FY 2004 Targets
as much cooling benefit (in terms of core temperature reduction) as cooling continuously, but at a fraction of the MCS capacity. *Individual Protection, Masks* - Begin development of advanced mask concepts focusing on lightweight system integration, a wider range of protection, and improved thermal attenuation. Assemble advanced mask concept system for preliminary human factor studies. Initiate optimization of candidate sorbent media structures by the testing of media properties and the modification of that media to improve performance. Optimize candidate lens materials through the evaluation of chemical and physical properties and the modification of that material to enhance performance. Develop and evaluate new and improved mask technologies to improve protection, flow dynamics, heat and moisture transfer, and fogging. Identify appropriate aerosol generation and detection equipment, develop and validate test procedures, and conduct protection factor study using mask headform tester and controlled leaks. *IST, CB Battle Management* - Complete battle management Front End analysis. Expand studies to address data fusion approaches for multiple sensors. Assess value added at system-level (multiple networked CB sensors and non-CB sensors) through modeling and demonstration. Initiate examination of methods to improve real-time, network-aided decision making, and visualization of network responses. *IST, CB Environment* - Improve next-generation model (MESO) to include wet biological modifications, improve accuracy over rough terrain, and further improvements to boundary layer atmospheric physics. Evaluate performance of computational fluid dynamics model (CBW-CFX) on ships and fixed land structures and identify areas for improvement. Demonstrate performance of coupled weather/CBW dispersion model. Evaluate performance of hazard evolution codes updated by agent environmental effects data. *IST, CB Planning, Training, Analysis* - Demonstrate HLA or DIS application of hazard models. Conduct statistical analysis of results of agent toxicity load variation in several hazard prediction models for fixed site application. *IST, Simulation Based Acquisition* - Initiate testing of prototyping models against highest priority CBD objects. Develop and demonstrate a breadboard virtual prototype system (VPS). *SS&T, Aerosol Technology* - Continue to measure quantitative performance of candidate aerosol collectors for advanced point biological and chemical detection technology, and operating at the Joint Service low temperature requirement (-28 degrees F). Fabricate and	technology, and operating at the Joint Service low temperature requirements (-28 degrees F). Design an omnidirectional inlet that performs satisfactorily under all conditions, including high wind speeds. Optimize design, and begin to fabricate second generation brassboards using mini-machining technologies to reduce size, power consumption, and weight of aerosol components in order to meet the stringent requirements for advanced detection systems. Continue to provide biological and chemical simulant aerosols and expand capability to include wider range of aerosol sizes and feed stocks in preparation for Joint Field Trials. *SS&T, Threat Agents* - Publish a Front End Analysis (FEA) based on the prior year assessment of long-term needs in threat agent data and needs for improved simulants in CB defense materiel development. Continue to synthesize, toxicologically screen, and characterize identified new threat materials and fill identified data gaps for established chemical and biological threat agents. Continue to characterize fundamental properties of Y. pestis and initiate work on B. mallei. Load bioinformatics database with fundamental non-medical properties. Complete validation studies on simulant BG spores and improvement of Erwinia herbicola antigenicity and continue research on a new viral simulant. Continue development of an agent/simulant knowledge base technical information system. *Low Level Chemical Agent Operations Toxicology Studies Determine* (limited) concentration-time profile for agent potency ratio for miosis and lethality in non-rodent animals. Complete GB lethality studies in non-rodent animals. Continue to resolve technological challenges in generating and sampling very low concentrations of VX. Begin development of GD vapor generation and analytical chamber systems. Expand use of chemical agent dose metrics assay in blood and tissue samples after inhalation exposure to GD and novel chemical agents.

FY 2003 Targets	FY 2004 Targets
test the first brassboards of advanced aerosol inlets to meet Joint Service requirements for high collection efficiency over the respirable particle size range and for wind speeds up to 60 mph. Fabricate and test the first brassboards of a new generation of aerosol concentrators and collectors using mini-machining technology to reduce the size, power consumption, and weight of aerosol components in order to meet the stringent requirements for advanced detection systems. Continue to provide controlled biosimulant aerosol challenges and begin providing chemical agent simulant aerosol challenges for Joint Service, DARPA, and DOE experimental equipment in preparation for Joint Field Trials. *SS&T, Threat Agents* - Complete the assessment of long-term needs in threat agent data and needs for improved simulants in CB defense materiel development, and participate in a collaborative inter-agency laboratory program to fill the data gaps and improve simulants. Continue to synthesize, toxicologically screen, and characterize identified new threat materials and fill identified data gaps for established chemical and biological threat agents. Initiate characterization of fundamental properties of Y. pestis. Develop a secure database environment for bioinformatics. Continue assessment of bacteria persistence. Complete research on new simulants for novel chemical threat agents. Continue research on simulant BG spores and improvement of simulant Erwinia herbicola. Initiate research for a new viral simulant. Continue development of an agent/simulant knowledge base technical information system with emphasis on collection of biological agent and simulant data and quality assessment of chemical and biological agent and simulant data. *Low Level Chemical Agent Operations Toxicology Studies* - Complete non-rodent GB inhalation studies to characterize Ct relationships for low level, longer duration exposures. Complete methodology development for VX inhalation exposures and initiate VX studies in rats. Continue dose-metric methodology efforts to understand internal dosage following exposures. Develop methods applicable to physiological modeling for understanding the impact of route of exposure on toxicological effects from low level concentration and extended duration exposures to nerve agents.	

3.5.1.6 Assessment of Chemical and Biological Defense Applied Research. Applied research efforts in FY2002 for project CB2 are at least minimally effective. Many areas of CB defense applied research were successful. The assessment is based on two factors: (1) two DTOs in this area was rated yellow by the TARA and one was rated red. All efforts have developed plans to

address concerns identified and will be re-assessed in FY2003. (2) Several technologies successfully transitioned to advanced development. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2002.

3.5.2 Medical Biological Defense Applied Research (Project TB2)

This project funds applied research on the development of vaccines, therapeutic drugs, and diagnostic capabilities to provide an effective medical defense against validated biological threat agents including bacteria, toxins, and viruses. Innovative biotechnological approaches and advances will be incorporated to obtain medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Categories for this project include Defense Technology Objectives (DTO); science and technology programs in medical biological defense (diagnostic technology, bacterial therapeutics, toxin therapeutics, viral therapeutics, bacterial vaccines, toxin vaccines, and viral vaccines); and directed research efforts (medical countermeasures, genetically engineered threat countermeasures, and vaccines).

3.5.2.1 TB2 Performance Goal (Outcome). The goal of CB defense medical biological defense applied research is to increase scientific understanding of the mechanisms and processes involved in the pathogenesis of BW agents in order to develop preventive and therapeutic protection and diagnostic technologies for BW agents.

3.5.2.2 TB2 Outcome Measure

TB2 is minimally effective when	TB2 is successful when
• The results provide fundamental information in support of new and improved defensive systems, including information on – Bacterial Therapeutics, – Toxin Vaccines, – Bacterial Vaccines, – Toxin Therapeutics, – Viral Therapeutics, – Viral Vaccines, – Diagnostic Technologies, and – Protocols to Enhance Biological Defense. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs are rated GREEN by the TARA Panel.

3.5.2.3 Metric Description. The metric for TB2 is described in Section 3.2.1.1. Applied research also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annexes E of Volume I, *DoD Chemical and Biological Defense Program Annual Report to Congress.*

3.5.2.4 TB2 Actual and Planned Performance:

FY2002 Targets	Actual Performance
Diagnostic Technologies - Prepare diagnostic reagents that will enhance the depth and diversity of current approaches for the rapid recognition of infection by potential	*Common Diagnostic Systems (DTO)* - Completed system integration and verification of approaches, reagents, and protocols for portable devices capable of detecting and identifying nucleic acids from a broad range of biological threat agents in clinical specimens.

FY2002 Targets	Actual Performance
biological threat agents. Evaluate preclinical models and standards for evaluating medical diagnostic systems prior to transition to the regulatory-compliant medical laboratory. *Bacterial Therapeutics* - Optimize and correlate in vitro assays with animal models for selected antibiotic and nonantibiotic therapeutics for bacterial threat agents; examine effects of selected therapies on multiple agent exposures in an animal model. *Toxin Therapeutics* - Initiate structural stabilization and formulation studies on lead inhibitors of botulinum and SE toxin activity. Refine in vivo and standardize in vitro screening models for botulinum toxin and SE intoxication. *Viral Therapeutics* - Assess the potential for immunotherapy against Ebola virus in nonhuman primate models. Complete investigation of mechanisms of Ebola and MBGV pathogenesis in nonhuman primate models to characterize promising surrogate markers of efficacy for therapies. *Bacterial Vaccines* - Optimize in vitro correlate assays for candidate vaccines against various bacterial threat agents; evaluate the efficacy of additional novel component vaccine candidates (i.e., fusion proteins and antigen cocktails). Optimize formulation and dosage regime of selected vaccine candidates in animals. *Toxin Vaccines* - Determine whether the recombinant fragment C vaccine candidates can elicit protective immunity in mice against neurotoxins produced by various strains of Clostridium botulinum. *Viral Vaccines* - Define the correlates of immunity (i.e., neutralizing antibody, cytotoxic T cells) that protect against disease from MBGV. Develop assays to measure "surrogate markers" to validate the efficacy of vaccine candidates in established model systems for MBGV. *Vaccines* - Enhance applied research toward innovative approaches for the development and delivery of next generation and generation-after-next vaccines and strategies to enhance the immune response to broad classes of biological threats. *Medical Countermeasures* - Enhance applied research efforts toward the development of	*Medical Countermeasures for Brucella (DTO)* - Tested most efficacious vaccine candidate against Brucella abortus (B. abortus) and B. suis in the mouse lung infection model. Tested efficacy against B. melitensis of additional live vaccine candidates in the mouse lung infection model. Continued to develop and validate in vitro systems in mice and higher animal species to reliably quantify the intensity of potentially protective immune responses and determine the immune system components that eliminate infection with candidate vaccines. *Medical Countermeasures for Encephalitis Viruses (DTO)* - Completed development of higher animal species models for Venezuelan equine encephalitis (VEE) virus type 3A. Redirected eastern equine encephalitis (EEE) and western equine encephalitis (WEE) virus vaccine development back to discovery and focused DTO on a multivalent VEE vaccine candidate. *Multiagent Vaccines for Biological Threat Agents (DTO)* - Completed improvements to the naked DNA and VEE replicon vaccine delivery platforms to optimize their use as multiagent vaccines and combined VEE replicon vaccine platforms for botulinum neurotoxin A, anthrax protective antigen, and Marburg virus into a multiagent vaccine construct. *Needle-less Delivery Methods for Recombinant Protein Vaccines (DTO)* - Evaluated formulations for intranasal, inhalational, and transdermal application of recombinant proteins intended for use as vaccines. Evaluated novel commercial adjuvants in combination with vaccine candidates. Evaluated in animal models, proprietary vaccine delivery devices with commercial partners. *Recombinant Plague Vaccine Candidate (DTO)* - Completed determination of the range of protection of the recombinant plague vaccine candidate against other virulent strains of Yersinia pestis (plague) in animals. *Recombinant Protective Antigen (rPA) Anthrax Vaccine Candidate (DTO)* - Completed the evaluation of isoform biological activity. Completed the determination of formaldehyde requirement for stable rPA vaccine preparations. Continued to develop the mouse potency assay and determination of the in vitro correlate of immunity for the rPA vaccine candidate. Developed antibodies to rPA in higher animal species to support continuing passive immunity studies. Provided technical summaries to the information package supporting entry of the rPA vaccine into component advanced development. *Diagnostic Technologies* - Continued preparation of diagnostic reagents to enhance the depth and diversity of current approaches for the rapid recognition of infection by potential biological threat agents. Assessed preclinical models and standards for evaluating medical diagnostic systems prior to transition to the regulatory compliant medical laboratory. *Therapeutics, Bacterial* - Optimized and correlated in vitro assays with animal models for selected antibiotic and other therapeutics for bacterial threat agents and examined effects of selected therapies on multiple agent exposures in an animal model. Studied

FY2002 Targets	Actual Performance
broad-spectrum therapeutic countermeasures for exposure to broad classes of biological threats. *Genetically Engineered Threat Medical Countermeasures* - Expand genetic and protein databases to identify and catalogue the various virulence factors, toxic motifs and host regulatory proteins responsible for the pathologic effects of biological threat agents. Continue research efforts such as curating the genetic information base, evaluating mechanisms of pathophysiology associated with toxin threats and developing critical proteomics capability.	the effect of immunomodulators on the host response to B. mallei and Y. pestis candidate vaccines and identified modulators effective in enhancing candidate vaccines. *Therapeutics, Toxin* - Initiated structural stabilization and optimization studies on selected lead inhibitors of botulinum neurotoxin and staphylococcal enterotoxin B (SEB) toxin activity; optimized the structure of best peptide-based inhibitor of botulinum neurotoxin serotype A. Tested more than 2,800 compounds for the potential to inhibit botulinum neurotoxin serotype A. Produced and evaluated prototype activity-based assays to screen inhibitors of botulinum neurotoxin serotypes D, E, and F. Applied botulinum neurotoxin activity-based assay technology toward the development of an activity-based assay for inhibitors of anthrax lethal toxin. Refined ex vivo and standardized in vitro screening models for botulinum toxin and SEB intoxication. *Therapeutics, Viral* - Assessed the potential for immunotherapy against Ebola virus in higher animal species models. Completed investigation of mechanisms of Ebola virus pathogenesis in higher animal species models to characterize promising surrogate markers of efficacy for therapies. Initiated research for development of a variola (smallpox) animal model at the Centers for Disease Control and Prevention (CDC). *Vaccines, Bacterial* - Optimized in vitro correlate assays for candidate vaccines against various bacterial threat agents and evaluated the efficacy of additional novel component vaccine candidates (i.e., fusion proteins and antigen cocktails). Optimized formulation and dosage regime of selected vaccine candidates in animals. Determined whether plasmids expressing foreign genes in a virulent Brucella lead to suitable attenuation and immunogenicity in mice. *Vaccines, Toxin* - Demonstrated that recombinant vaccine candidates, based on the botulinum toxin heavy chain (Hc) subunit, can elicit protective immunity in mice against neurotoxins produced by various strains of Clostridium botulinum. *Vaccines, Viral* - Determined that markers of immunity (i.e., antibody) did not correlate with protection against disease from divergent strains of Marburg virus. Developed higher animal species models for western equine encephalitis (WEE) virus. *Medical Countermeasures* - Enhanced applied research efforts toward the development of broad-spectrum therapeutic countermeasures for exposure to various classes of biological threats. *Genetically Engineered Threat Medical Countermeasures* - Expanded genetic and protein databases to identify and catalogue the various virulence factors, toxic motifs, and host regulatory proteins responsible for the pathologic effects of biological threat agents. Continued curating the genetic information database, evaluating mechanisms of pathophysiology associated with toxin threats, and developing critical proteomics capability. *Vaccines* - Enhanced applied research toward innovative approaches for the development and delivery of next generation and generation-after-next vaccines and strategies to enhance the immune response to various classes of biological threats.

3.5.2.5 TB2 Future Targets

FY 2003 Targets	FY 2004 Targets
Medical Countermeasures for Brucella (DTO) - Determine whether over-expression of vaccine antigens in candidate live vaccines increases protective efficacy. Continue to develop and validate in vitro systems in mice and higher animal species to reliably quantify the intensity of potentially protective immune responses and determine the immune system components that eliminate infection complications following use of live attenuated candidate vaccines. *Medical Countermeasures for Encephalitis Viruses (DTO)* - Complete studies on production of the live, attenuated VEE vaccine virus constructs, their genetic stability, and transmission potential of candidate VEE virus vaccines in competent vector mosquitoes. *Needle-less Delivery Methods for Recombinant Protein Vaccines (DTO)* - Downselect formulations for intranasal, inhalational, and/or transdermal delivery of recombinant protein vaccines. Propose commercial or proprietary device for delivery of vaccines. *Diagnostic Technologies* - Apply new diagnostic approaches to the early recognition of infection, adapting the technologies to current and future comprehensive integrated diagnostic systems. Apply new technological approaches for diagnosis of potential biological warfare threat agents in laboratory studies using relevant clinical samples. Apply new technological approaches for concentrating and processing clinical samples to support rapid biological agent identification. Apply research reagents and associated assays for the detection of appropriate biological markers using relevant clinical samples. *Therapeutics, Bacterial* - Evaluate novel antibiotics and other therapeutics in established in vitro assays and animal models. Establish a database of therapeutic profiles for various species of bacterial threat agents. *Therapeutics, Toxin* - Continue high-throughput assessment of candidate therapeutic inhibitors for botulinum neurotoxin. Complete testing and development of cell-free assay for assessment of candidate therapeutic inhibitors of staphylococcal enterotoxin (SE). Select lead candidate inhibitors based upon results in cell-free and cell-based assays and prepare toxin-inhibitor crystals for x-ray diffraction analysis. Evaluate the outcome of structural stabilization and optimization studies on lead inhibitors of botulinum and SE. *Therapeutics, Viral* - Continue assessing the potential for immunotherapy against Ebola virus in higher animal species models. Identify pharmacological compounds provided by industry that disrupt filovirus growth in cell culture. Assess therapeutic action of compounds in mouse and higher animal models of filovirus infection. Continue research for development of a variola animal model at CDC. *Vaccines, Bacterial* - Develop mutants in various agents for in vivo expressed genes to examine role in virulence. Characterize	*Diagnostic Technologies* - Continue to apply new diagnostic approaches directed toward early recognition of infection, selecting technologies that can be adapted to current and future comprehensive integrated diagnostic systems. Continue laboratory studies using relevant clinical samples to apply new technological approaches for diagnosis of potential biological warfare threat agents. Continue to apply new technological approaches for concentrating and processing clinical samples to support rapid agent identification and to apply research reagents and associated assays for the detection of appropriate biological markers using relevant clinical samples. *Therapeutics, Bacterial* - Perform additional in vivo studies on efficacy of selected antimicrobial compounds against various bacterial threat agents in small animal models. *Therapeutics, Toxin* - Initiate testing of lead inhibitors of botulinum neurotoxin and SE using in vivo model systems for assessment of therapeutic efficacy. Standardize in vivo model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy. *Therapeutics, Viral* - Continue the assessment for immunotherapy for filoviruses. Identify pharmacological compounds provided by industry that may intervene in filovirus-induced shock. Assess therapeutic action of compounds in mouse models of filovirus infection. Complete research for development of a variola animal model at CDC. *Vaccines, Bacterial* - Continue to evaluate potential live-attenuated glanders vaccine candidates in small animal models. Perform preliminary studies in the development of an acellular brucella vaccine candidate. Continue to perform in vitro and in vivo studies to support advanced development of the rPA vaccine candidate (i.e., phase 2 clinical trials). *Vaccines, Toxin* - Qualify in vivo and in vitro concept model systems for assessment of rRTA vaccine candidate efficacy and surrogate endpoints of human clinical efficacy. *Vaccines, Viral* - Initiate applied research to define correlates of immunity that protect against disease from filoviruses (Marburg and Ebola viruses) and from alphaviruses (EEE and WEE viruses).

FY 2003 Targets	FY 2004 Targets
the mechanism(s) of vaccine resistance in selected strains of various agents. Determine mechanisms and correlates of protection with efficacious glanders vaccines. In support of rPA vaccine candidate entry into component advanced development, complete evaluation of immunogenicity and efficacy of rPA isoform species in the rabbit model; continue to develop reagent standards for use in an in vitro potency assay; and complete collection of immune serum for evaluation in a higher animal species passive transfer study. In support of recombinant plague vaccine development, complete development of anti-V antigen competitive enzyme-linked immunosorbent assay (ELISA) and cytotoxicity inhibition assays; complete determination of the range of protection of the vaccine candidate against other virulent strains of Y. pestis in animals; and complete studies in mice on alternate vaccine administration routes, dose, formulation and mucosal adjuvants. *Vaccines, Toxin* - Complete efficacy studies on recombinant ricin toxin A-chain (rRTA) vaccine candidates and downselect to two lead candidates. Scale up process development for rRTA vaccine candidates; conduct analytical test qualification for identity and stability studies of rRTA candidates; and develop potency assay for rRTA vaccine candidates. *Vaccines, Viral* - Assess mechanism of immunity that protects against disease from Ebola virus in lower animal models. Develop assays to measure markers to validate the efficacy of vaccine candidates in established model systems for Ebola virus. Develop higher animal species models for EEE virus. *Medical Countermeasures* - Accelerate research to define criteria for successful therapeutics against toxins and viruses to obtain diverse compounds such as inhibitors, channel-blockers, natural product extracts, and peptides that show promise as potential therapeutics against botulinum neurotoxins, staphylococcal enterotoxin, ricin toxin, and viruses. Continue characterizing and refining the variola higher animal model for smallpox for use in determining the effectiveness of post-exposure therapies. *Genetically Engineered Threat Medical Countermeasures* - Accelerate research efforts directed toward compiling and prioritizing function-related structural elements that constitute known toxins and virulence factors of biological threat agents. Continue developing integrated databases of protein domains or three-dimensional structural elements identified as virulence factors in biological threat organisms. *Vaccines* - Evaluate additional vaccine candidates for delivery using the multiagent delivery platform. Develop virus constructs and obtain commercially produced humanized mouse monoclonal antibodies to evaluate protective immune responses. Investigate the potential of live vaccine candidates for bacterial threat agents.	

3.5.2.6 Assessment of Medical Biological Defense Applied Research. Applied research efforts in FY2002 for project TB2 were effective. Many areas of medical biological defense applied research were successful. The assessment for success is based on the assessment of the TARA panel that most DTOs in this area were rated green. One DTO was rated yellow. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2002.

3.5.3 Medical Chemical Defense Applied Research (Project TC2)

This project funds medical chemical defense applied research and emphasizes the prevention of chemical casualties through application of pharmaceuticals for prevention and treatment of the toxic effects of nerve, blister, respiratory, and blood agents. This project supports applied research of prophylaxes, pretreatments, antidotes, skin decontaminants, and therapeutic compounds that will counteract the lethal, physical, and behavioral toxicities of chemical agents. It also supports development of medical chemical defense materiel that ensures adequate patient care, field resuscitation, and patient management procedures. Categories for this project include Defense Technology Objectives (DTOs), science and technology program areas (Pretreatments, Therapeutics, and Diagnostics), and directed research efforts (Low Level Chemical Warfare Agent Exposure and Fourth Generation Agents).

3.5.3.1 TC2 Performance Goal (Outcome). The goal of medical chemical defense applied research is to increase scientific understanding of the mechanisms of action and effects of CW agents in order to demonstrate and develop technologies for preventive and therapeutic protection and diagnostics.

3.5.3.2 TC2 Outcome Measure

TC2 is minimally effective when	TC2 is successful when
• The results provide fundamental information in support of new and improved defensive systems, including information on – diagnostics, – low-level toxicology, – pre-treatments, – therapeutics, – novel threats, – optical recognition technologies, – new detection technologies. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs are rated GREEN by the TARA Panel.

3.5.3.3 Metric Description. The metric for TC2 is described in Section 3.2.1.1. Applied research also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annexes E of Volume I, *DoD Chemical and Biological Defense Program Annual Report to Congress.*

3.5.3.4 TC2 Actual and Planned Performance:

FY2002 Targets	Actual Performance
Diagnostics - Modify currently fielded cholinesterase testing kit to more efficiently test a large sample load. *Pretreatments* - Develop animal models to test scavenger candidates efficacy. Conduct characterization studies. Begin preliminary efficacy studies with next generation nerve agent scavengers. Continue development of potential transgenic/ bioengineered sources of next generation nerve agent. *Therapeutics* - Assess candidate agents in suitable animal models of soman-induced status epilepticus for efficacy in saving vulnerable neurons and improving neurobehavioral outcome. Develop criteria for evaluating neuronal salvage after status epilepticus. Determine the essential ingredients for a rinse solution to optimally treat HD-induced ocular injury. Evaluate improved animal models for screening candidate combination therapies. *Low Level Chemical Warfare Agent Exposure* - Study biological markers for indicating prior low dose exposures and investigate selectivity of the markers for chemical warfare agents. *Non-Traditional Agents* - Assess the efficacy of new proposed nerve agent countermeasures. Prioritize potential approaches for improving effectiveness of new nerve agent countermeasures. Evaluate oxime effectiveness against Fourth Generation Agents. Evaluate newly identified anticonvulsants for improved survival after exposure to NTAs. Assess the effects of in vivo persistence of NTAs on current countermeasure efficacy. Confirm cardiac pathology seen after exposure to NTAs.	*Chemical Agent Prophylaxis II (DTO)* - Initiated discussions with the Food and Drug Administration (FDA) to establish the type(s) of data required for submission with an investigational new drug application for a human recombinant catalytic protein. Identified sources of human butyrylcholinesterase (HBuChE) for purification. Prepared sufficient amounts of purified HBuChE to test efficacy in two animal models. *Medical Countermeasures for Vesicant Agents II (DTO)* - Evaluated improved animal models for screening candidate combination therapies for sulfur mustard (HD) exposure. Defined side effects, established adversity levels, and collated available industrial documentation. In addition, evaluated potential treatments for HD-induced pulmonary injury under controlled conditions. Studied the hairless mouse as a model for evaluating the effectiveness of pretreatments and therapies against cutaneous HD exposure. Tested antagonists of apoptosis and studied their effectiveness in blocking HD-induced cytotoxicity. *Diagnostics* - Modified cholinesterase testing assay technology to generate diagnostic information on large sample sizes. *Pretreatments* - Continued investigation of potential transgenic/bioengineered enzyme for production of next generation nerve agent catalytic scavenger. Identified/ developed animal models for tests of new scavenger candidate(s). Initiated preliminary efficacy studies with scavengers of nerve agents. Renewed identification of a cyanide pretreatment/treatment compound. Pursued the expression and purification of a recombinant human carboxylesterase for crystallization. Purified a potential antidote for organophosphate poisoning. *Therapeutics* - Developed criteria for evaluating neuronal damage and recovery after status epilepticus. Evaluated improved animal models for screening combinations of anticonvulsant candidate therapies. Determined the potential effect(s) of combinations of anticonvulsants. Determined the essential ingredients for a rinse solution to optimally treat HD-induced ocular injury. Investigated modulation of intracellular calcium as a strategy for protecting against soman-induced seizure related brain damage. Evaluated commercially available licensed wound healing products. *Low Level Chemical Warfare Agent (CWA) Exposure* - Continued to study biological markers of low dose exposures and investigated selectivity of the markers for CWAs. Evaluated potential genetic and central nervous system perturbations following low level CWA exposures. Initiated studies of the effects of chronic exposure to low doses of CWAs in cellular energy

FY2002 Targets	Actual Performance
	systems and esterases in guinea pig brain. Developed a behavioral component model in guinea pig for studying the effects of low dose chronic exposure to CWAs. *Non-Tradiotional Agents (NTAs)* - Assessed the efficacy and prioritized potential approaches for improving the effectiveness of newly proposed nerve agent countermeasures. Evaluated oxime effectiveness against NTAs. Evaluated newly identified anticonvulsants for improved survival after exposure to NTAs. Assessed the effects of in vivo persistence of NTAs on current countermeasure efficacy. Confirmed cardiac pathology seen after exposure to NTAs. Initiated mechanistic studies of oxime reactivation of novel agents-inhibited butyrylcholinesterase. Studied the effectiveness of pretreatment and treatment countermeasures on emerging organophosphorous compounds. *SBIR*-Small Business Innovative Research Efforts

3.5.3.5 TC2 Future Targets

FY 2003 Targets	FY 2004 Targets
Medical Countermeasures for Vesicant Agents II (DTO) - Identify therapeutic window for administering compounds to mitigate the effects of HD exposure. Evaluate combination therapies for HD exposure in animal models. *Diagnostics* - Pursue development of an ocular device for self-examination of pupillary response to nerve agent exposure. Continue development of analytical methods to measure biological matrices (e.g., blood, urine, tissue) following CWA exposure. Develop confirmatory forensic diagnostic capabilities and rapid screening technology for field applications. *Pretreatments* - Develop physiological pharmacokinetic models of CWAs. Evaluate the safety and circulatory stability of recombinant bioscavengers. Determine specific carbohydrate structures of human serum butyrylcholinesterase for reference material for Good Laboratory Practices (GLP) and current Good Manufacturing Practices (cGMP) production. Generate serum carboxylesterase-deficient mice for use in testing efficacy of nerve agent bioscavengers. Evaluate several classes of compounds that behave by different mechanisms of action, to include methemoglobin formers and sulfur donors, to pursue development of a cyanide pretreatment. *Therapeutics* - Evaluate new FDA-approved drugs for treatment of HD-induced ocular injury. Optimize formulation for an ocular rinse that treats HD-induced ocular injury. Evaluate treatments for HD-induced pulmonary injury. Develop experimental protocol to evaluate drugs, drug combinations and drug treatment	*Pretreatments* - Determine toxicokinetics of CWAs and the impact of pretreatment in guinea pigs. Determine x-ray crystallographic structure of catalytic scavengers. *Therapeutics* - Determine efficacy of midazolam and anticholinergic drug combinations against seizures and lethality caused by nerve agents. Test FDA-approved drugs shown to be neuroprotective in both anatomic and behavioral studies. Conduct screening of candidate antivesicant compounds. Determine minimal amount of atropine needed to sustain survival in higher animal species exposed to nerve agent. Develop in vitro and in vivo models to support efficacy studies of new antivesicant countermeasures. *Diagnostics* - Initiate development of diagnostic applications for miniaturized mass spectrometer. Investigate applicability of ocular device for self-examination of pupillary response. Develop diagnostics that can be used to diagnose exposure via respiratory route. Refine analytical methods to measure scopolamine levels in blood and tissue. *Low Level Chemical Warfare Agent Exposure* - Confirm heritable physiological and biochemical correlates of low sarin sensitivity. Utilize in vitro human cellular, tissue and biomolecular dosing model to study low level chemical exposure of HD and/or nerve agent. Evaluate potential prophylactic and therapeutic compounds to treat effects of low level chemical exposure. Validate genetic alterations following low level chemical exposure. Complete analysis of cellular damage following low level chemical exposure. Test prophylactic and therapeutic compounds as

FY 2003 Targets	FY 2004 Targets
protocols with potential to control nerve agent-induced seizures. Evaluate ability of midazolam and anticholinergics to terminate nerve agent-induced seizures in a higher animal species model. Evaluate antagonists of apoptosis and the blockade of HD-induced toxicity. Examine modulation of intracellular calcium to protect against soman-induced seizure related brain damage. Develop and test neuroprotectant drugs to protect against status epilepticus following nerve agent exposure. Assess alternate higher animal species as models for nerve agent toxicity and medical countermeasures. *Low Level Chemical Warfare Agent Exposure* - Identify prophylactic and therapeutic compounds to treat low level chemical exposure using in vitro cellular model. Utilize a behavioral assessment model in guinea pigs to study the effects of low level chemical warfare agent exposure. *Non-Tradiotional Agents (NTAs)*- Evaluate cardiac toxicity following NTA toxicity in cardiac muscle cells and animal models. Synthesize and screen oxime reactivation compounds for nerve agents. Consider anti-organophosphate antibodies as an FGA treatment strategy. Evaluate bioscavenger pretreatment as medical countermeasure against NTAs in guinea pigs.	countermeasures to low level chemical exposure in animal models. *Non-Tradiotional Agents (NTAs)*- Synthesize new oximes effective against NTAs. Evaluate candidate anticonvulsants for effective dose, time to terminate seizures, and neurochemical changes following NTA exposure. Develop surrogate markers for alternative NTA medical countermeasures in guinea pigs. Determine efficacy of candidate NTAmedical countermeasures in higher animal species.

3.5.3.6 Assessment of Medical Chemical Defense Applied Research. Applied research efforts in FY2002 for project TC2 are effective. Many areas of medical chemical defense applied research were successful. The assessment for success is based on the assessment of the TARA panel that all DTOs in this area were rated green. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2002.

3.6 ADVANCED TECHNOLOGY DEVELOPMENT (PROGRAM ELEMENT 0603384BP)

This program element demonstrates technologies that enhance the ability of U. S. forces to defend against, and survive CB warfare. This PE funds advanced technology development for Joint Service and Service- specific requirements in both medical and non- medical CB defense areas. The medical program aims to produce drugs, vaccines, and medical devices as counter-measures for CB threat agents. Specific areas of medical investigation include: prophylaxis, pretreatment, antidotes and therapeutics, personnel and patient decontamination, and medical management of casualties. In the non- medical area, the focus is on demonstrations of CB defense technologies, including biological detection, chemical detection, and decontamination. These demonstrations, conducted in an operational environment with active user and developer participation, integrate diverse technologies to improve DoD CBW defense and deterrence. These demonstrations are leveraged by the Counterproliferation Support Program and include remote Biological Detection. Work conducted under this PE transitions to and provides risk reduction for Advanced Component Development and Prototypes (PE 0603884BP) and System

Development and Demonstration (PE 0604384BP) activities. The work in this PE is consistent with the Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan. This PE also provides for the conduct of advanced technology development in the areas of real- time sensing, accelerated BW operational awareness, and the restoration of operations following a BW/ CW attack. This program is dedicated to conducting proof- of- principle field demonstrations, and tests of system- specific technologies to meet specific military needs.

3.6.1 Chemical and Biological Defense Advanced Technology Development (Project CB3)

This project demonstrates technology advancements for Joint Service application in the areas of chemical and biological agent detection and identification, decontamination, and individual/collective protection, which will speed maturing of advanced technologies to reduce risk in system-oriented Advanced Component Development and Prototypes efforts. This project funds the Joint Service Family of Decontamination Systems (JSFDS) Program, the Joint Service Sensitive Equipment Decontamination (JSSED) Program, the Joint Chemical/ Biological Agent Water Monitor (JCBAWM), the Joint Biological Standoff Detection System (JBSDS), the Joint Service Wide Area Detector (JSWAD), and Joint Operational Effects Federation (JOEF).

3.6.1.1 CB3 Performance Goal (Outcome). The goal of the CB defense non-medical advanced technology development program is to increase scientific understanding and demonstrate advanced capabilities of the mechanisms and processes involved in the detection, protection against, and decontamination of CBW agents.

3.6.1.2 CB3 Outcome Measure

CB3 is minimally effective when	CB3 is successful when
• The results provide fundamental information and demonstrate improved capabilities in support of new and improved defensive systems, including information and capabilities for: – Advanced materials for individual protection, – Detection of chemical and biological contamination, – Decontamination of sensitive equipment, – Early warning chemical and biological detection capabilities • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs rated GREEN by the TARA panel

3.6.1.3 Metric Description. The metric for CB3 is described in Section 3.2.1.1. Advanced technology development also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annexes A–D of Volume I, *DoD Chemical and Biological Defense Program Annual Report to Congress.*

3.6.1.4 CB3 Actual and Planned Performance:

FY2002 Targets	Actual Performance
JSSED - Evaluate Block II/III technologies. Perform agent chamber/panel tests to validate performance of candidate technologies on a variety of surfaces. Address material compatibility issues. Initiate documentation of technology findings to support transition to development.	*Chemical and Biological Warfare Effects on Operations (DTO-CB43)* - Continued development of a general purpose model of the operations of large fixed-site facilities (air bases, Aerial Ports of Debarkation (APODs) and, Seaports of Debarkation

FY2002 Targets	Actual Performance
JSFXD Block III - Conduct down selection screen of candidate skin decontamination identified in the FEA. Compare to baseline M-291 kit. Candidate technologies include the nanoemulsion system developed by the DARPA program and a foam system developed under the Department of Energy Chemical Biological National Security Program. Transition optimal candidate(s) to JSFXD Advanced Component Development and Prototypes phase for insertion into the FDA approval process. *Foam Based Decontamination Systems* - Conduct evaluation of and modify the DOE foam based decontamination system to meet military challenge levels. Extend the test bed to include Fourth Generation Agents. *Detection Technologies* - Complete assessment of hyperspectral imaging technologies and establish transition points for the highest potential payoff capabilities. *Portable Chemical/Biological Detection Technologies* - Initiate evaluation of technologies from all sources for feasibility in application to military requirements for potentially man-portable multi-agent chemical and biological detectors with reduced logistics burden. The effort will focus on performance characterization and chamber test with identification of technological shortfalls. Specific initial candidates include DOE micro-CB lab, pyrolysis-GC/IMS, optical particle classifier. *Biological Detection Technologies* - Develop assays and initiate live agent testing of DARPA Micro Array of Gel-Immobilized Compounds (MAGIChip) nucleic acid identification technology for Bacillus species. Initiate automation of DARPA-developed ultraviolet-infrared matrix-assisted laser desorption (MALDI) mass spectrometry (MS). Initiate comparative evaluation for sensitivity and discrimination capability of UV-MALDI and UV-IR MALDI MS candidates from DARPA and electrospray ionization (ESI) MS using aerosol collections in chamber tests. Identify sample processing challenges for improvement. *Joint Field Trials* - Expand the biological Joint Field Trial concept to a multi-tiered set of evaluation protocols to facilitate the characterization of candidate technology at varying levels of maturity.CB Modeling/Simulation - Accelerate development and demonstration of models describing impacts of CBW on site operations. *Technology Transition* - Conduct acceptance testing of anthrax antibody mixtures under development for improved affinity. Complete testing of upconverting phosphors. Implement improved sample treatment procedures for MALDI-TOF mass spectrometer and prepare for field evaluation.	(SPODs)), with the capability to represent chemical and biological warfare (CBW) attacks and their operational impacts. Demonstrated Initial Operational Capability (IOC) for fighter bases. *Miniaturized C/B Detectors (MEMS Technology)* - Initiated a feasibility study on the use of chemically modified microspheres to detect the presence of select biological agents. Prototypes were configured as a reader and interchangeable assay cartridges that contains the microspheres. *CB Standoff Detection* - Completed testing and evaluation of selected hyperspectral systems. *Decontamination, Sensitive Equipment* - Completed Analysis of Alternatives (AoA) for JSSED Blocks II/III. Conducted a thermal decon feasibility study for aircraft and other combat vehicle interiors. Developed a detailed aircraft materials database in support of JSSED Blocks II/III. *Decontamination, Future Threat Agent Studies* - Completed stirred reactor kinetic studies of fielded and developmental decontaminants on non-traditional threat agents. *Information Systems Technology (IST), Joint Effects Model (JEM)* - Initiated analysis of alternatives and preparation of documentation to support transition to development. Initiated combination of candidate hazard prediction models to single model, and began preparations to demonstrate capability. *IST, Joint Operational Effects Federation (JOEF)* - Initiated Analysis of Alternatives (AoA) and market survey. Established Joint System Architecture IPT and Joint T&E IPT. Initiated creation of the Test and Evaluation Master Plan (TEMP). Began preparation to demonstrate the maturity of the JOEF Blk I federate. Initiated Interoperability Assessment and a System Threat Assessment. *Tech Transition* - Developed improved sample processing methodologies for UV MALDI-TOF mass spectrometer. Initiated production of upconverting phosphors (UCP) and tickets for test and evaluation. Identified and initiated evaluation of candidate antibodies for specificity and sensitivity against anthrax. Initiated development of catalytic oxidation filtration device. Initiated development of infrared MALDI-TOF mass spectrometer for improved pathogen discrimination. Initiated reformulation and evaluation of Sandia foam for applications to military decontamination. Initiated test and evaluation of Sandia gas microchem lab for vapor agent detection and assessment of fluidic microchem lab for biological detection. Initiated

FY2002 Targets	Actual Performance
	development of improved sample handling technology for incorporation into handheld automated nucleic acid analyzer (HANAA). Assessed performance of anthrax MAGIChip (MicroArray of Gel Impregnated Compounds).

3.6.1.5 CB3 Future Targets

FY 2003 Targets	FY 2004 Targets
Detection of Agent in Water - Complete design and initiate build of brassboard system for demonstration. *Chemical and Biological Warfare Effects on Operations (DTO-CB43)* - Complete and transition Joint Effects Model to the Joint Warning and Reporting Network (JWARN). Complete and transition Simulation, Training and Analysis for Fixed Sites (STAFFS) to Joint Warfare Simulation (JWARS) and to JOEF Block I. *Decontamination, Sensitive Equipment* - Complete the validation, verification, and accreditation process for the JSSED Block II/III AoA. Complete development and management plan for items identified by the AoA and complete TRL 4/5 requirements. Develop MS-B transition documentation. *Decontamination, Future Threat Agent Studies* - Conduct contact hazard evaluations using NATO protocols. Conduct off-gas hazard evaluations using NATO/TTCP protocols. *IST, Joint Operational Effects Federation (JOEF)* - Complete Analysis of Alternatives (AoA) and market survey. Complete the Test and Evaluation Master Plan (TEMP). Complete the acquisition strategy and supporting acquisition documentation. Complete Interoperability Assessment and System Threat Assessment. Prepare final documentation for transition to development. *Field Trials* - Conduct Technology Readiness Evaluations (TRE) of point and standoff CB detection systems. *Tech Transition* - Develop improved sample processing interface for UV MALDI-TOF mass spectrometer and incorporate into DARPA BioTOF device. Complete evaluation of upconverting phosphors for bio identification. Complete evaluation of anthrax-specific antibodies previously identified. Evaluate and refine catalytic oxidation filtration device. Initiate development of pathogen agents database with UV/IR MALDI and construct automated sample processing interface. Complete evaluation of Sandia foam for military decon. Refine gas microchem lab and initiate development of improved sample processing interface for fluidic microchem lab. Complete development of sample handling interface for HANAA. Extend MAGIChip	*Detection of Agent in Water* - Continue build of brassboard system for demonstration. *Oxidative Decontamination Formulation (DTO-CB44)* - Demonstrate products with existing applicator systems. Modify or develop alternative applicators. Conduct basic integration of products into a "simulated environment." Conduct robust chamber studies using full-scale conceptual system testing with live agents. *CB Point Detection, Biological Identification* - Mature next generation broad-spectrum discrimination and automated ID technologies toward demonstration in field test environment. *CB Standoff Detection, Integrated Detection* - Conduct comparative testing of competing surface contamination and wide spectral range detection systems. *Decontamination, Solution Chemistry* - Conduct an analysis of alternatives for solution chemistry approaches. Complete the validation, verification, and accreditation process for the AoA and complete an advanced development and management plan for items identified. *Decontamination, Future Threat Agent Studies* - Conduct stirred reactor, contact hazard and off gas testing on emerging decontaminants not tested previously. *IST, Joint Operational Effects Federation (JOEF)* - Demonstrate the maturity of the JOEF Blk I, complete supporting acquisition documentation and transition to development. *IST, Virtual Prototyping Suite (VPS)* - Initiate Analysis of Alternatives (AoA) and market survey for solutions for an eventual Virtual Prototyping Suite. Establish Joint System Architecture IPT and Joint T&E IPT. Initiate creation of the Test and Evaluation Master Plan (TEMP). *Field Trials* - Conduct Technology Readiness Evaluations (TRE) of point and standoff CB detection systems. *Tech Transition* - Complete development of integrated UV MALDI-TOF and IR MALDI-TOF mass spectrometers. Complete catalytic oxidation filtration

FY 2003 Targets	FY 2004 Targets
capability to address additional pathogen agents. Initiate assessment of additional technologies in detection, decontamination, and filtration from other government agencies. *Evaluation of Technologies for Non Traditional Agents (NTA)* - Continue assessment of point detector modifications, development of spectral data-base, and evaluation of fielded decontamination systems against NTA.	device. Integrate air sampler with fluidic micro chemlab. Complete evaluation of MAGIChip. Continue assessment of technologies in detection, decontamination, and filtration from other government agency programs.

3.6.1.6 Assessment of Chemical and Biological Defense Advanced Technology Development. Advanced Technology Development efforts in FY2002 for project CB3 were effective. Many areas of CB defense advanced technology development were successful. The assessment for success is based on the assessment of the TARA panel that all DTOs in this area were rated green. Extensive development continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2002.

3.6.2 WMD Civil Support Team Advanced Technology Development (Project CM3)

This project funds Pre- Systems Acquisition in support of Consequence Management teams around the Nation. National Guard Weapons of Mass Destruction Civil Support Teams (WMD CST) are being established in every state. These teams were created based upon the Defense Reform Initiative Directive #25 (DRID #25), Integrating National Guard and Reserve Component Support for Response to Attacks Using Weapons of Mass Destruction (WMD). The role of the Civil Support Teams (CSTs) were further codified in the National Security Strategy of October 1998, which builds upon the National Guard's ties to the communities throughout the nation, and its long- standing tradition of responding to national emergencies. The strategy allows the National Guard to provide forces and resources that the emergency manager requires to manage the potentially catastrophic effects of a WMD situation. The National Guard, as the lead organization for military support to local and state authorities, leverages its geographic dispersion across the nation to reduce response times, and allow for the majority of the country to be protected. As a result of Presidential and Secretary of Defense directives, the Department of Defense established the Weapons of Mass Destruction Civil Support Teams (WMD CST) to rapidly respond in support of a local incident commander to assess a suspected WMD incident scene, advise them of appropriate courses of action that will protect local populations from loss of life, injury, and significant property damage, and facilitate the development of their requests for assistance (RFAs) based on CST knowledge of available local, state and federal resources that can assist in the mitigation of a WMD emergency. This program funds the purchase and testing of commercial-off-the-shelf (COTS) components on the existing Table of Distribution and Allowances (TDA) of WMD CST, and evaluates new commercial products being considered for the WMD CST TDA for performance and ability to meet requirements.

3.6.2.1 CM3 Performance Goal (Outcome). The goal of the WMD-CST advanced technology development program is to demonstrate advanced capabilities and concepts involved in the detection, protection against, and decontamination of CBW agents.

3.6.2.2 CM3 Outcome Measure

CM3 is minimally effective when	CM3 is successful when
• The results provide fundamental information and demonstrate improved capabilities in support of new and improved defensive systems, including information and capabilities for: – Biological detection systems. – Critical reagents for biological detection and identification. • The results of research are published in peer-reviewed journals or presented at scientific conferences. • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed.	• Information, technologies, or processes are transitioned to applied research or advanced technology development. • All DTOs are rated GREEN by the TARA.

3.6.2.3 Metric Description. The metric for CM3 is focused on providing improved capabilities to the WMD Civil Support Teams. Success accomplishment of research will result in transitioning of projects to the Civil Support Teams and support of DoD's homeland security mission.

3.6.2.4 CM3 Actual and Planned Performance:

FY2002 Targets	Actual Performance
No planned program	Researched detection strategies of bioweapons use in the human population. Gene chip technology was investigated to help determine, in as little as a few hours, if a human was exposed to, and infected by, a biological agent. Tested blood to see which specific genes are turned on in response to infection by the disease organism.

3.6.2.5 CM3 Future Targets

FY 2003 Targets	FY 2004 Targets
Initiate purchase of COTS components on the Table of Distribution & Allowances (TDA) of the WMD CSTs. Initiate evaluation of new commercial products being considered for TDA to determine performance and ability to meet WMD CST requirements. Planning and support for test program for commercial equipment.	Continue evaluation of new commercial products being considered for TDA to determine performance and ability to meet WMD CST requirements. Initiate targeted technology Analysis of Alternatives for DoD civil support to WMD Consequence Management response for follow- on technology insertion options.

3.6.2.6 Assessment of WMD-CST Advanced Technology Development.

FY03 new start. Hence, no assessment of FY02 provided.

3.6.3 Counterproliferation Support Advanced Technology Development (Project CP3)

The mission of the Counterproliferation Program (CP) is to address shortfalls in the DoD deployed capability to defend against and counter the proliferation of WMD. By focusing on near term results, the CP accelerates delivery of new tools, equipment, and procedures to combat forces. Under the passive defense pillar, CP enhances the efforts of the Chemical and Biological Defense Program. This project funds a variety of programs to defend our forces against WMD,

such as the Biological Detection (BIODET), Biological Non-Systems (BIO Non Sys) efforts, Critical Reagents Program (CRP), Restoration of Operations (RESTOPS) and a Planning and Development for Advanced Concept Technology Demonstrations.

3.6.3.1 CP3 Performance Goal (Outcome). The goal of the counterproliferation support advanced technology development program is to demonstrate advanced capabilities and concepts involved in the detection, protection against, and decontamination of CBW agents.

3.6.3.2 CP3 Outcome Measure

CP3 is minimally effective when	CP3 is successful when
• The results provide fundamental information and demonstrate improved capabilities in support of new and improved defensive systems, including information and capabilities for: – Biological detection systems. – Critical reagents for biological detection and identification. • The results of research are published in peer-reviewed journals or presented at scientific conferences. • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed.	• Information, technologies, or processes are transitioned to applied research or advanced technology development. • All DTOs are rated GREEN by the TARA.

3.6.3.3 Metric Description. The metric for CP3 is described in Section 3.2.1.1. Advanced technology development also includes several specific projects that are identified as Defense Technology Objectives (DTOs), which are detailed and assessed separately (See section 3.3). DTOs funded under this project include the Restoration of Operations (RestOps) ACTD and the Contamination Avoidance as Sea Ports of Debarkation (CASPOD) ACTD.

3.6.3.4 CP3 Actual and Planned Performance:

FY2002 Targets	Actual Performance
ACTD-PD - Perform technology maturity evaluations, perform analysis of alternative technologies, and prepare acquisition strategy for Contamination Avoidance for Seaports of Debarkation (CASPOD) Advanced Concept Technology Demonstration. *BIO Non Sys* - Initiate development and testing of improved UV detectors, UV micro-lasers, and algorithms. Initiate prototype development and testing of an optical based detector using high affinity nucleic acid aptamer chips. Initiate challenges to detector systems in development using Red Teams. Initiate development and testing of a new improved collector/concentrator and pre-separator devices for filtering and cleaning environment air samples. *BIO Non Sys* - Continue development and evaluation of generic detectors (TOF MS/MS, UV) and associated algorithms to provide increased warning time for tactical battlefield applications. Continue development, testing, and evaluation of automated sample preparation technology and protocols for PCR devices to improve identification specificity and sensitivity in future biological systems. *BIO Non Sys* - Develop decontaminants, equipment, procedures, techniques, and tactics for decontamination of wide	*CASPOD* - Developed exercise scenarios for CASPOD ACTD, performed a Table Top Exercise for CB defense of a Seaport for CASPOD Operational Sponsor, initiated CONOPS development by the Operational Sponsor of CASPOD ACTD, performed management support functions for the CASPOD ACTD. *RestOps* - Demonstrated the decontamination procedure of a wide body aircraft at Eglin AFB and demonstrated decontamination applicators using current Aircraft SPO approved decontaminants and two proposed decontaminants. *RestOps* - Performed agent transfer tests and wind tunnel tests for agent studies applicable to procedures to be used in the RestOps ACTD demonstration. Developed training computer based interactive training tools for the RestOps ACTD. Supported RestOps technology vignette efforts at Osan Airbase and Dugway Proving Ground.

FY2002 Targets	Actual Performance
body and other aircraft	*Joint Service Installation Pilot Project (JSIPP)* - Performed assessments on nine installations for the JSIPP project. Modeled locations for biological detection equipment.

3.6.3.5 CP3 Future Targets

FY 2003 Targets	FY 2004 Targets
CASPOD - Perform technical testing of technologies for the CASPOD ACTD. *CASPOD* - Develop and test techniques, tactics, and procedures for the use of the CASPOD ACTD technologies. Acquire test equipment, provide test participants and evaluators, develop environmental compliance documentation for tests and preliminary demonstration.	n/a

3.6.3.6 Assessment of Counterproliferation Support Advanced Technology Development. Advanced Technology Development efforts in FY2002 for project CP3 were at least minimally effective. The CASPOD ACTD was initiated during FY02. However, both ACTDs were assessed as yellow by the TARA panel. In addition, the JSIPP program was initiated during FY2002 to provide enhanced force protection at military installations.

3.6.4 Medical Biological Defense Advanced Technology Development (Project TB3)

This project funds preclinical development of safe and effective prophylaxes and therapies (vaccines and drugs) for pre- and post- exposures to biological threat agents. This project also supports the advance d technology development of diagnostic devices to rapidly diagnose exposure to biological agents in clinical samples. A broad range of technologies involved in the targeting and delivery of prophylactic and therapeutic medical countermeasures and diagnostic systems is evaluated so that the most effective countermeasures are identified for transition to Advanced Development. Transitioning candidate vaccines, therapeutics, and diagnostic technologies to Advanced Development requires the development of scientific/ regulatory technical data packages to support the Food and Drug Administration (FDA) Investigational New Drug (IND) process and DoD acquisition regulations. Categories for this project include Defense Technology Objectives (DTOs); science and technology program areas in medical biological defense (diagnostic technology, bacterial therapeutics, toxin therapeutics, viral therapeutics, bacterial vaccines, toxin vaccines, and viral vaccines), directed research efforts (Bioadhesion Research, Medical Chemical/ Biological Counterterrorism Support, Medical Countermeasures, Advanced Diagnostics, and Vaccines); and efforts to transition promising medical biological defense technologies from DARPA.

3.6.4.1 TB3 Performance Goal (Outcome). The goal of the medical biological defense advanced technology development program is to increase scientific understanding and demonstrate advanced capabilities of the mechanisms and processes involved in the preventive and therapeutic countermeasures and diagnostics for BW agents.

3.6.4.2 TB3 Outcome Measure

TB3 is minimally effective when	TB3 is successful when
• The results provide fundamental information and demonstrates advanced capabilities in support of new and improved defensive systems, including: – Bacterial Therapeutics, – Toxin Vaccines, – Bacterial Vaccines, – Toxin Therapeutics, – Viral Therapeutics, – Viral Vaccines, – Diagnostic Technologies, and – Protocols to Enhance Biological Defense. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs are rated GREEN by the TARA

3.6.4.3 Metric Description. The metric for TB3 is described in Section 3.2.1.1. Advanced technology development also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annex E of Volume I, *DoD Chemical and Biological Defense Program Annual Report to Congress.*

3.6.4.4 TB3 Actual and Planned Performance:

FY2002 Targets	Actual Performance
Diagnostic Technologies - Compare new diagnostic reagents, devices, and protocols in preclinical studies before transition to the regulatory-compliant medical laboratory. Evaluate candidate diagnostic technologies in field-based studies and in a highly regulated medical center clinical laboratory prior to transitioning to Advanced Component Development and Prototypes. *Bacterial Therapeutics* - Evaluate in animal models selected immunomodulators in combination with efficacious antibiotics for protection against bacterial threat agents. *Toxin Therapeutics* - Optimize formulation and pharmacodynamics of lead candidate licensed drugs that also inhibit SE-induced intoxication. *Viral Therapeutics* - Continue evaluating formulations or prodrugs to overcome problems with metabolism, bioavailability, or pharmacokinetics of compounds with otherwise acceptable antiviral profiles for orthopox and filoviruses.	*Common Diagnostic Systems (DTO)* - Completed an analysis of alternatives of portable nucleic analysis systems for detecting and identifying nucleic acids from a broad range of biological threat agents in clinical specimens. Prepared technical data package to support transitioning the common diagnostic systems candidate out of technology base and preparation of a medical device application to the FDA. *Medical Countermeasures for Brucella (DTO)* - Prepared pilot lot of lead live attenuated vaccine candidates using processes consistent with the intent of current Good Manufacturing Practices (cGMP) and used the pilot vaccine lot to perform pre-investigational new drug (IND) animal studies. Determined relative efficacy of lead candidates against brucella melitensis in higher animal species challenge model. *Medical Countermeasures for Encephalitis Viruses (DTO)* - Elicited sufficient cross protective immunity in higher laboratory animals to satisfy Operational Requirements Document (ORD) requirement for immunity against VEE virus types IE. Provided product development support for producing human-use vaccine substrate for anticipated Phase 1 trial. Redirected eastern equine encephalitis (EEE) and

FY2002 Targets	Actual Performance
Bacterial Vaccines - Validate correlates of immunity for protection against B. anthracis; evaluate vaccine candidates and correlates of immunity for B. mallei. *Toxin Vaccines* - Complete formulation studies on a combinatorial recombinant pentavalent botulinum toxin vaccine. Initiate formulation studies on a combinatorial SE vaccine. Complete development of reagents and assays to determine the quality and quantity of recombinant botulinum and SE vaccines during process development. Initiate the process development (60 L scale-up) for botulinum toxin serotypes D and G in the Pichia yeast system and complete efficacy studies. Initiate the process development for SE serotype A and complete efficacy studies. Initiate in vivo concept model systems for assessment of vaccine efficacy and surrogate endpoints of human clinical efficacy for botulinum toxin and SE intoxication. *Viral Vaccines* - Determine optimal dose and schedule for vaccination against MBGV. Demonstrate in pivotal animal studies that the vaccine candidate is efficacious against aerosol infection with MBGV. *DARPA Program Transition* - Expand DARPA transition efforts to include novel molecular method for selecting vaccine antigens, additional antiviral agents, and evaluation of plant-based antibodies as therapeutic agents. *Vaccines* - Enhance advanced technology development efforts toward innovative approaches for the development and delivery of next generation and generation-after-next vaccines and strategies to enhance the immune response to broad classes of biological threats. *Medical Countermeasures* - Enhance advanced technology development efforts toward the development of broad-spectrum therapeutic countermeasures for exposure to broad classes of biological threats. *Advanced Diagnostics* - Enhance advanced technology development efforts toward the development of advanced medical diagnostic capabilities.	western equine encephalitis (WEE) virus vaccine development back to discovery and focused the DTO on a multivalent VEE vaccine candidate. *Multiagent Vaccines for Biological Threat Agents (DTO)* - Completed testing for safety and efficacy in animal models of candidate products (individually and combined) intended for use in a multiagent vaccine. *Needle-less Delivery Methods for Recombinant Protein Vaccines (DTO)* - Assessed the quantitative relationships between toxin-specific antibodies or other indicators of immunity in mucosal surfaces and blood. Continued standardization of animal models for evaluating novel adjuvants and vaccine delivery systems. *Recombinant Plague Vaccine Candidate (DTO)* - Performed vaccine efficacy studies in two higher animal species models against aerosol and parental challenges to resolve which is the most appropriate model for demonstrating the protective capability of the vaccine *Recombinant Protective Antigen (rPA) Anthrax Vaccine Candidate (DTO)* - Investigated enhancement of the rPA vaccine candidate with immunostimulatory compounds. Evaluated rPA-induced protective immunity against several diverse geographical isolates of B. anthracis. *Diagnostic Technologies* - Compared new diagnostic reagents, devices, and protocols in preclinical studies before transitioning to the regulatory compliant medical laboratory. Evaluated candidate diagnostic technologies in field-based studies and in a regulated medical center clinical laboratory prior to transitioning out of technology base. Developed and evaluated new diagnostic assays for biological warfare threat agents and successfully transitioned selected assays to the PEO-CBD and Health and Human Service partners. Enhanced advanced medical diagnostic capabilities for presymptomatic detection of biological warfare agent (BWA) infection. *Therapeutics, Bacterial* - Evaluated, in animal models, selected immunomodulators in combination with efficacious antibiotics for protection against bacterial threat agents. *Therapeutics, Toxin* - Evaluated lead candidate licensed therapeutic drugs that also inhibit staphylococcal enterotoxin B (SEB)-induced intoxication. *Therapeutics, Viral* - Continued evaluating formulations or prodrugs to overcome problems with metabolism, bioavailability, or pharmacokinetics of compounds with otherwise acceptable antiviral profiles for orthopox viruses. *Vaccines, Bacterial* - Continued to identify and validate correlates of protective immunity against anthrax, plague, glanders, and brucella, in support of selected vaccine candidates. *Vaccines, Toxin* - Continued scaled up production of

FY2002 Targets	Actual Performance
	recombinant botulinum neurotoxin vaccine candidates. Performed formulation studies on a recombinant SEB vaccine. Completed the development of reagents and assays to support process development of recombinant botulinum, ricin, and SEB vaccines. Initiated process development for botulinum neurotoxin vaccine candidates. Supported process development for SE serotype A (SEA) and completed efficacy studies. Planned transition of SEA and SEB vaccine candidates out of technology base. Developed mutant recombinant ricin toxin A-chain (rRTA) antigens for potential use as vaccine candidates and initiated efficacy studies. *Vaccines, Viral* - Determined that the Marburg vaccine candidate was unable to protect against divergent strains of Marburg virus. Initiated investigation of other vaccine strategies for the Marburg group of viruses. *Defense Advanced Research Projects Agency (DARPA) Program Transition* - Continued expansion and definition of medical biological defense technologies transitioned from DARPA. Initiated studies of a small molecule antibiotic effective against anthrax. Initiated research on a B-cell based diagnostic sensor technology for viral and bacterial pathogens. Initiated studies of a superantigen toxin antagonist and developed a screening assay to identify additional compounds. *Bioadhesion Program* - Continued to evaluate mechanisms that block the adhesion of pathogens to host cells thereby preventing infection or intoxication. Defined protective epitopes and novel delivery systems for use in vaccine formulations focusing on bioadhesion. Used phage display peptide libraries to identify peptide mimetics and constructed vaccine candidates consisting of covalent conjugates and nanoparticles displaying those peptide mimetrics. Characterized immune responses in humans exposed to inhalation and cutaneous anthrax to identify the most immunogenic epitopes. Used microarray technology to characterize the genetic response profiles of vaccinated and/ or BWA challenged animals leading to effective immunity. *Medical Countermeasures* - Enhanced advanced technology development of broad-spectrum therapeutic countermeasures for exposure to various biological threats. *Advanced Diagnostics* - Enhanced advanced technology development efforts toward the development of advanced medical diagnostic capabilities for early presymptomatic detection of BWA infection. *Vaccines* - Enhanced advanced technology development and delivery of next-generation and generation-after-next vaccines and strategies, which will enhance the immune response to various classes of biological threats.

3.6.4.5 TB3 Future Targets

FY 2003 Targets	FY 2004 Targets
Medical Countermeasures for Brucella (DTO) - Demonstrate effectiveness of candidate vaccine in higher animal species challenge model for protective efficacy against a single pathogenic brucella species. Prepare a technical data package supporting transition of the optimum brucella vaccine candidate out of technology base. *Medical Countermeasures for Encephalitis Viruses (DTO)* - Identify final formulation of a trivalent VEE vaccine. Perform formulation and vaccine interference studies for VEE multivalent vaccine (for protection against VEE IA/B, VEE IE, VEE 3A). Perform potency and stability studies on VEE vaccine components. Support development of technical data package that addresses FDA requirements for an Investigational New Drug application and that supports transitioning the multivalent VEE vaccine candidate out of technology base. *Needle-less Delivery Methods for Recombinant Protein Vaccines (DTO)* - Perform initial efficacy studies for single recombinant protein delivered by alternate route(s). Propose monovalent vaccine formulations for intranasal, inhalational, and/or transdermal delivery systems. Propose in vitro correlate of immunity for surrogate endpoint of clinical efficacy. *Recombinant Plague Vaccine Candidate (DTO)* - Continue expanded studies in higher animal species for immunogenicity and efficacy and down-select the best higher animal species model. Continue studies to optimize vaccine production and formulation to support entry of the vaccine candidate into component advanced development. Complete a revised technical data package based on completed studies, to facilitate transition of the vaccine candidate out of technology base. *Diagnostic Technologies* - Continue comparing alternative diagnostic technologies in laboratory-based and field-based studies prior to transition to the field medical laboratory. Compare overlapping diagnostic technologies that can be integrated into a single comprehensive platform capable of identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies. Continue to develop, evaluate, and transition diagnostic assays to the PEO CBD in support of JBAIDS block I acquisition program. Identify immunodiagnostic technology options offering performance and design characteristics sufficient to address JBAIDS requirements. Demonstrate technical capability for detection of at least three biological agents (toxins) within two hours. *Therapeutics, Bacterial* - Conduct comparative assessment for safety and efficacy of immunomodulators and other types of broad-spectrum compounds against multiple bacterial threat agents.	*Needle-less Delivery Methods for Recombinant Protein Vaccines (DTO)* - Propose formulation/ device/route for delivery of combination of multiple recombinant proteins. Perform definitive efficacy studies on monovalent vaccine in second animal model. Evaluate in vitro correlate of immunity. *Diagnostic Technologies* - Continue to compare alternative diagnostic technologies in laboratory-based and field-based studies prior to transition to the field medical laboratory. Continue to compare overlapping diagnostic technologies that can be integrated into a single comprehensive platform capable of detecting and identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies. Continue to develop, evaluate, and transition diagnostic assays to PEO CBD in support of the JBAIDS acquisition program. Complete inter-laboratory evaluation of top performing immunodiagnostic technology(ies). *Therapeutics, Bacterial* - Continue assessment of selected compounds for safety and efficacy against multiple bacterial threat agents in small animal models. *Therapeutics, Toxin* - Standardize in vivo concept model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy for botulinum and SE intoxication. Test FDA-approved drugs for septic shock as adjunct SE therapeutics in vivo. *Therapeutics, Viral* - Complete the evaluation of one antiviral drug formulation for orthopox viruses. Continue evaluating second drug formulation or prodrugs for orthopox viruses. *Vaccines, Bacterial* - Continue to perform animal studies which support transition of potential vaccine candidates to advanced development. Perform studies to address the mechanism of protective cellular immunity induced by selected vaccine candidates. Continue animal studies supporting phase 2 clinical trials and complete developmental work on the mouse potency assay in support of rPA vaccine candidate development. *Vaccines, Toxin* - Conduct toxicity assays, activity assays, and efficacy studies for lead rRTA vaccine candidates. Continue laboratory stability studies of the lead rRTA candidate; initiate rRTA candidate higher animal species protocol and model development. *Vaccines, Viral* - Select the best vaccine candidate based on ability to protect against filoviruses.

FY 2003 Targets	FY 2004 Targets
Therapeutics, Toxin - Prepare sufficient amounts of lead inhibitors of botulinum toxin and SEB intoxication for testing ex vivo or in vivo. Evaluate feasibility of drugs approved by FDA for septic shock as adjunct SE therapeutics using in vitro assays. *Therapeutics, Viral* - Evaluate the combined approach of antiviral drug therapy and immunotherapy in treatment of disease from filoviruses. Continue evaluating formulations or prodrugs to overcome problems with metabolism, bioavailability, or pharmacokinetics of compounds with otherwise acceptable antiviral profiles for orthopox viruses. *Vaccines, Bacterial* - Initiate a comparison of the safe and most efficacious vaccine candidates against select agent exposures. Analyze study data to determine best glanders vaccine candidate(s). Incorporate data for brucella and plague vaccine candidates into technical data packages for these vaccine candidates. Continue assay support and studies on adjuvants and formulations in support of rPA vaccine candidate entry into component advanced development; continue to evaluate the efficacy of rPA immunity against B. anthracis strains of diverse geographic origins; and continue long-term rPA efficacy studies in rabbits and higher animal species. *Vaccines, Toxin* - Complete process development for botulinum toxin serotypes D and G in the Pichia yeast system. Support advanced development of recombinant SEB vaccine candidate by transitioning laboratory assays and data out of the technology base. *Vaccines, Viral* - Test promising vaccine strategies in higher animal species for the ability to protect against filoviruses (Marburg and Ebola viruses). Complete research studies for the development of vaccine candidates for WEE virus. *Defense Advanced Research Projects Agency (DARPA) Program Transition* - Continue expansion and definition of medical biological defense technologies transitioned from the DARPA. Complete lead optimization of a small molecule antibiotic, complete in vitro and in vivo safety and efficacy studies, and continue Investigational New Drug (IND) enabling studies. Develop two additional B-cell lines and extend the B-cell based diagnostic sensor technology to include toxin agents. Evaluate superantigen toxin antagonists in vitro assays. Use plant expression vectors to create transgenic whole-plant systems expressing plague vaccine antigens. Produce monoclonal antibodies directed against Ebola virus in transgenic plants (plantibodies). Optimize two classes of bacterial RNA-binding compounds with broad-spectrum antimicrobial activity. Apply DNA shuffling technology to identify novel antigens that show protection in mice against at least two encephalitic alphaviruses.	Continue research for the development of vaccine candidates for EEE virus infection. Test promising vaccine candidates for WEE in animal systems. *Defense Advanced Research Projects Agency (DARPA) Program Transition* - Continue expansion and definition of medical biological defense technologies transitioned from the DARPA. Complete chemical manufacturing and control studies and file the IND for a small-molecule antibiotic effective against anthrax. Develop four additional B-cell lines and evaluate the B-cell based diagnostic sensor technology on clinical samples. Develop a blood assay for the superantigen toxin antagonists. Optimize the plant lines and obtain milligram-quantities of plague vaccine antigens from multiple plant species for in vivo evaluation. Obtain milligram-quantities of Ebola plantibodies for in vitro and in vivo evaluation. Complete lead optimization of bacterial RNA-binding compounds and conduct in vitro and in vivo evaluation of the most effective compounds. Evaluate DNA vaccines developed from the most cross-reactive antigens, obtained through DNA shuffling, in higher animal species for protection against three encephalitic alphaviruses.

3.6.4.6 Assessment of Medical Biological Defense Advanced Technology Development. Advanced technology development efforts in FY2002 for project TB3 are effective. Many areas of medical biological defense applied research were successful. The TARA panel rated two DTOs in this area as yellow, primarily due to aggressive schedule risk. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2002.

3.6.5 Medical Chemical Defense Advanced Technology Development (Project TC3)

This project supports the investigation of new medical countermeasures to include antidotes, pretreatment drugs, and topical skin protectants to protect U. S. forces against known and emerging CW threat agents. Capabilities are maintained for reformulation, formulation, and scale- up of candidate compounds using current good laboratory practices. Analytical stability studies, safety and efficacy screening, and preclinical toxicology studies are performed prior to full-scale development of promising pretreatment or treatment compounds. Categories for this project include Defense Technology Objectives (DTOs), science and technology program areas (Pretreatments, Therapeutics, and Diagnostics), and directed research efforts (Low Level Chemical Agent Exposure and Fourth Generation Agents).

3.6.5.1 TC3 Performance Goal (Outcome). The goal of the medical chemical defense advanced technology development program is to increase scientific understanding and demonstrate advanced capabilities of the mechanisms and processes involved in the preventive and therapeutic countermeasures and diagnostics for CW agents.

3.6.5.2 TC3 Outcome Measure

TC3 is minimally effective when	TC3 is successful when
• The results provide fundamental information and demonstrate advanced capabilities in support of new and improved defensive systems, including information on – chemical agent therapeutics, – chemical agent prophylaxes, – chemical agent diagnostics, – novel threat agents, – low level operational toxicology. • The results of research are published in peer-reviewed journals or presented at scientific conferences • Key research efforts are reviewed by an independent panel of experts and the quality and relevance of the efforts are assessed	• Information, technologies, or processes are transitioned to applied research or advanced technology development • All DTOs are rated GREEN by the TARA.

3.6.5.3 Metric Description. The metric for TB3 is described in Section 3.2.1.1. Advanced technology development also includes several specific Defense Technology Objectives (DTOs), which are described in Chapter 2 and Annex E of Volume I, *DoD Chemical and Biological Defense Program Annual Report to Congress.*

3.6.5.4 TC3 Actual and Planned Performance:

FY2002 Targets	Actual Performance
Diagnostics - Test a prototype noninvasive monitor that measures oxyhemoglobin, deoxyhemoglobin, methemoglobin, and carboxyhemoglobin via finger, ear, or toe. *Pretreatments* - Complete development/validation of a transgenic animal model capable of producing sufficient amounts of recombinant enzyme scavenger material for clinical trials. Produce nerve agent scavengers in transgenic models and test for safety and efficacy in two animal species. Complete physiologically based pharmacokinetic model studies of expected human efficacy with various scavengers to assist in an IPR downselect process. *Therapeutics* - Determine optimal combination of midazolam and anticholinergic drug and order of administration to obtain maximal anticonvulsant effect against seizures in a nonhuman primate model. Conduct studies directed at obtaining FDA approval for an ocular rinse that optimally treats mustard-induced injuries. Select combination therapy approaches that provide highest level of protection in animal models for safety and efficacy advanced screening. Conduct pharmacokinetics and formulation studies of vesicant countermeasure candidates. Study efficacy and safety of vesicant countermeasure candidates. Determine window of opportunity for administration of therapy(s) for blister agent HD exposure *Non-Traditional Agents (NTAs)* - Begin downselect process of best available countermeasure(s) against NTAs. Initiate formulation and bulk production feasibility efforts	*Active Topical Skin Protectant (aTSP) (DTO)* - Completed aTSP formulation studies and demonstrated efficacy against estimated exposure levels of chemical warfare agents (CWAs). Selected candidate(s) for transition out of technology base. Developed an M8 chemical agent paper test to evaluate effectiveness of topical skin protectant after challenge with CWAs. Developed and utilized a spectrophotometric method for proof of decontamination of the aTSP. Evaluated the efficacy of candidate aTSPs against cutaneous vapor and liquid sulfur mustard (HD). *Chemical Agent Prophylaxis II (DTO)* - Established higher animal species models to evaluate lead scavengers for safety and efficacy. Pursued development of behavioral safety testing procedures in higher animal species for chemical defense prophylactics. Evaluated and characterized enzyme identified as candidate for transition out of the technology base. Studied the effects of pretreatment with human butyrylcholinesterase scavengers on the toxicokinetics and binding of chemical warfare nerve agents in guinea pigs and marmosets. Completed program studies and initiated preparation of a technical data package to address Food and Drug Administration (FDA) requirements for an Investigational New Drug (IND) application that supports transition out of the technology base. *Medical Countermeasures for Vesicant Agents II (DTO)* - Studied combination therapy approaches to provide protection in animal models. Conducted pharmacokinetic and formulation studies of vesicant countermeasure candidates. Initiated collection of preclinical data that will allow a preliminary safety assessment of toxicokinetics (TK) and absorption, distribution, metabolism, and excretion (ADME) of proposed treatments. *Diagnostics* - Continued development of clinical laboratory and hand-held cholinesterase test devices. Evaluated commercially available off-the-shelf wound healing products for HD-induced injuries. *Pretreatments* - Completed development/validation of a process capable of producing sufficient amounts of enzyme scavenger material for clinical trials. Studied safety and efficacy of catalytic scavenger candidates. Conducted pharmacology and toxicology studies on candidate compounds. Continued physiological pharmacokinetics studies of the catalytic scavengers identified (carboxylesterase and paraoxonase-1).

FY2002 Targets	Actual Performance
	Therapeutics - Determined optimal midazolam anticonvulsant and anticholinergic drug combination and order of administration to obtain maximal anticonvulsant effect against seizures in a higher animal species model. Conducted studies designed to address FDA requirements to license ocular rinse that optimally treats HD-induced injuries. Selected combination therapy approaches that provide highest level of ocular protection and conducted safety and efficacy advanced screening in animal models. Studied efficacy and safety of vesicant counter-measure candidates. Defined pharmacokinetics of anticonvulsant compound for organophosphate-acetylcholinesterase inhibitors. Initiated design of equipment for evaluation of therapeutic agents for pulmonary edema formation in mice following CWA exposure. *Non-Traditional Agents (NTAs)* - Initiated downselection process of best available countermeasure(s) against NTAs. Initiated formulation and bulk production feasibility studies for countermeasures. Planned expedited effort to identify and characterize effective new cholinesterase reactivator compounds effective against NTAs. Initiated synthesis of new cholinesterase reactivator compounds for testing. Planned higher animal species study to establish effectiveness of new oxime. *SBIR*-Small Business Innovative Research Efforts

3.6.5.5 TC3 Future Targets

FY 2003 Targets	FY 2004 Targets
Medical Countermeasures for Vesicant Agents II (DTO) - Complete preclinical safety and efficacy studies of selected vesicant therapy candidate compounds. Complete pharmacokinetic studies of vesicant countermeasure candidates. Perform additional studies necessary to completely characterize candidate therapy. Transition vesicant therapeutic candidates out of the technology base. *Diagnostics* - Evaluate hand-held cholinesterase monitor for clinical use. Validate immobilized cholinesterases and nerve agent hydrolyzing enzymes as diagnostics for nerve agent exposure. *Pretreatments* - Complete physiological pharmacokinetic model studies of expected human efficacy with various catalytic scavengers. Verify adequacy of transgenic animal model to produce recombinant catalytic enzyme scavenger. *Therapeutics* - Select optimal anticholinergic drug for inclusion with midazolam anticonvulsant and establish optimal treatment protocol in higher animal species.	*Diagnostics* - Develop and test a non-invasive prototype instrument that measures methemoglobin via finger, ear, or toe. *Pretreatments* - Initiate evaluation of human protein catalytic scavenger. Utilize transgenic animal model to produce adequate amounts of recombinant catalytic enzyme scavenger for pre-clinical testing. *Therapeutics* - Determine efficacy of midazolam anticonvulsant and anticholinergic drug combinations against seizures and lethality produced by all current threat agents in the guinea pig model. Identify improved clinical strategies, such as skin grafting for HD wounds, for optimal treatment of CWA exposure and CWA contaminated conventional wounds. *Non-Traditional Agents (NTAs)* - Evaluate candidate oximes and anticonvulsants to treat NTA exposure. Document cardiac toxicity and recommend appropriate countermeasures. Perform pre-clinical safety studies of candidate NTA medical countermeasures.

FY 2003 Targets	FY 2004 Targets
Complete preclinical studies of selected vesicant therapy candidate compounds. Evaluate commercially licensed wound healing medical therapeutics for HD-induced injuries. Evaluate therapeutic agents for pulmonary edema produced by whole-body exposure to CWAs in animal models. *Non-Traditional Agents (NTAs)* - Compare all nerve agents for induction of neurochemical changes. Evaluate efficacy of anticonvulsants against NTAs. Identify mechanism of oxime reactivation of NTA-inhibited acetylcholinesterase.	*Low Level Chemical Warfare Agent Exposure* - Validate behavioral assessment model in guinea pigs to study the effects of low level chemical exposure. Correlate available data relating to low dose CWA exposure into a functional database suitable for predicting human toxicity.

3.6.5.6 Assessment of Medical Chemical Defense Advanced Technology Development. Advanced technology development efforts in FY2002 for project TC3 are effective. Many areas of medical chemical defense applied research were successful. The assessment for success is based on the assessment of the TARA panel that all DTOs in this area were rated green. Extensive research continues to be conducted in several research areas supporting several major operational goals detailed in Section 2 of the performance plan. Several new research projects and studies also were initiated in FY2002.

DOD CBDP DEFENSE MANAGEMENT PRACTICES

4.0 OVERVIEW OF CBDP MANAGEMENT PRACTICES

In Chapter 1 of the Annual Report to Congress on the DoD CBDP, the management and oversight structure of the DoD CBBP is described. In this year's report, the reorganization of the management and oversight structure is outlined as the structure is being implemented pursuant to the September 2002 Acquisition Decision Memorandum (ADM) signed by the Under Secretary of Defense for Acquisition, Technology, and Logistics, USD(AT&L). As the CBDP has matured over the past decade, this reorganization brings management efficiencies that will facilitate program management.

This section of the report focuses on management practices in support of **Corporate Goal 3: Oversee DoD NBC defense modeling and simulation efforts** and **Corporate Goal 4: Improve DoD NBC defense management practices – become a high performance organization**.

In support of Corporate Goal 3, this section outlines the management and oversight activities associated with the oversight of DoD NBC defense modeling and simulation efforts. Technical and operational accomplishments are described in other parts of the Annual Report.[5]

Activities in support of CBDP management activities are detailed in Budget Activity 6 (RDT&E Management Support) of the President's Budget Submission. Specific management projects (and project reference) are as follows:

- Antiterrorism support (AT6)
- WMD Civil Support Team (CM6)
- Joint Doctrine and Training Support (DT6)
- Dugway Proving Ground (DW6)
- RDT&E Management Support (MS6)
- Joint Point Test (O49)
- Small Business Innovative Research (SBIR)

4.1 CB DEFENSE MANAGEMENT PRACTICES – GOALS AND MEASURES

4.1.1 CB Defense Management and Oversight Outcome Measures

CB Defense Management and Oversight is…	
…minimally effective when…	**… successful when…**
• All DoD research, development, and acquisition (RDA) efforts have documented plans that are reviewed and contribute to operational goals. • DoD RDA efforts are coordinated among the Services and Defense Agencies. • All RDA programs are issued to the field with accompanying doctrine and training to ensure their effective application.	• Technologies are leveraged by other agencies to support homeland security and related missions. • Commericial or other available technologies are leverage to accelerate the development or fielding schedule of priority programs.

[5] See Chapter 2 and Annex B of Volume 1 and programs associated with Operational Goal 2 in Section 2 of Volume 2 for research, development, and acquisition accomplishments. See Chapter 4 of Volume 1 for accomplishments associated with operations, training, and readiness.

4.1.1.1 Metric Description. The metric for management and oversight is a qualitative assessment. This qualitative methodology for measuring the outcomes is allowed by the GPRA (31 USC 1115(b)) as an alternative to the quantitative performance measures. Successful oversight allows for the application of performance-based measures to ensure to appropriate balance among the complex and interrelated family of chemical and biological defense systems. The balance must be continually review to ensure the appropriate mix of capabilities for contamination avoidance, protection, and restoration, and among competing missions of passive defense, force protection, and consequence management, and also among the balance of near-term needs (procurement) versus long-term technological advancements (science and technology base.) An important element of the management and oversight success is what is not accomplished. That is, it is the role of management at times to make investment decisions and select among competing technologies, sometimes eliminating technologies that may have met the operational requirements though not as effectively as selected program, and sometime this means the elimination of funding for unsuccessful programs. Another key management metric is the successful coordination of research, development, and acquisition efforts among the many federal agencies pursuing similar efforts though for different missions (e.g. homeland security.)

4.1.1.2 Validation and Verification Methodology. A key oversight tool for management and oversight is the quarterly program oversight and evaluations of selected CB defense programs to ensure investments are on schedule, on budget, and meeting technical requirements (and taking corrective actions when they are not.)

4.1.2 Assessment of CB Defense Management and Oversight Outcome Measure

Overall, the DoD CBDP management and oversight has been effective, though many areas within the overall structure have required improvement to provide a more efficient approach. These changes are detailed in **Chapter 1** of Volume 1 of this report. Continued reports on the management and oversight process will be provided as the new structure is implemented during 2003.

4.2 CHEMICAL/BIOLOGICAL DEFENSE (RDT&E Management Support) (PROGRAM ELEMENT 0605384BP)

This program element provides research, development, testing and evaluation management support to the DoD Chemical and Biological Defense Program (CBDP). This effort includes support to the DoD response to CB terrorism; funds joint doctrine and training support; funds sustainment of technical test capability at Dugway Proving Ground (DPG); and funds financial/program management support. Additionally, this program element funds the Joint Point Test program (O49), which provides a response to Combatant Commanders and Services regarding joint tests and research assessments. Antiterrorism funding (AT6) provides DoD with a process and means to conduct assessments of installation vulnerabilities to CB threats. Weapons of Mass Destruction Civil Support Team (WMD-CST) (CM6) provides management funds to execute the Consequence Management Research Development Acquisition (RDA) program. Joint Training and Doctrine Support (DT6) funds development of Joint Doctrine and Tactics, Techniques, and Procedures for developing CB defense systems. The training and doctrine efforts also fund CB modeling and simulation to support the warfighter.

Dugway Proving Ground (DW6), a Major Range and Test Facility Base, funding provides for CB defense testing of DoD materiel, equipment, and systems from concept through production; to include a fully instrumented outdoor range capability for testing with simulants that can be precisely correlated to the laboratory testing with live agents. It finances indirect test operating costs not billable to test customers, including indirect civilian and contractor labor; repair and maintenance of test instrumentation, equipment, and facilities; and replacement of test equipment.

The management support program (MS6) provides management support for the DoD CBDP to allow program overview and integration of overall medical and non-medical programs by the Assistant to the Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ATSD(NCB)), through the Deputy Assistant to the Secretary of Defense for Chemical/Biological Defense (DATSD(CBD)); execution management by the Defense Threat Reduction Agency (DTRA); integration of Joint requirements, management of training and doctrine by the JRO-CBRN Defense; and Joint RDA planning, input to the Annual Report to Congress and Program Objective Memorandum (POM) Strategy Guidance development by the JPEO-CBD.

The management support program also funds the Joint Test Infrastructure Working Group (JTIWG) program to provide a mechanism to address test infrastructure and technologies needed to support Developmental Testing (DT) and Operational Testing (OT) of Department of Defense (DoD) CB defense systems and components throughout the systems' acquisition life cycle, as required in the RDA Plan. The JTIWG program funds a series of methodology, instrumentation, and associated validation programs to provide test infrastructure and technologies for testing RDA systems needed to support all services.

The Joint Point Test program (O49) funds provide planning, conducting, evaluating, and reporting on joint tests (for other than developmental hardware) and accomplishment of operational research assessments in response to requirements received from the Services and the Combatant Commanders for already fielded equipment and systems.

This Budget Activity also funds the Small Business Innovative Research (SBIR) program. The overall objective of the CBD SBIR program is to improve the transition or transfer of innovative CBD technologies between DoD components and the private sector for mutual benefit. The CBD program includes those technology efforts that maximize a strong defensive posture in a CB environment using passive and active means as deterrents. These technologies include CB detection; information assessment (identification, modeling, and intelligence); contamination avoidance; and protection of both individual soldiers and equipment.

4.2.1 CB DEFENSE (RDT&E Management Support) (Project AT6 – Antiterrorism Support)

The growing threat of the use of CB agents in acts of terrorism places DoD installations and personnel at a higher risk. With that in mind, this budget item provides DoD with the means to address the threat of CB terrorism to DoD installations and personnel. It attempts to address the requirements identified in PDD 39 and PDD 62. Funding provides for the development of combating CB terrorism planning, training, and exercise technologies; and the sustainment of those technologies in the out years, as appropriate. Sponsors of projects funded under this budget

item would include DTRA, J- 34, ASD (SO/LIC), SBCCOM, USA CMLS, the Technical Support Working Group, and other organizations involved with combating CB terrorism.

AT6 Actual and Planned Performance

FY2002 Targets	Actual Performance
Sustain combating CB terrorism technology development.	Performed planning and assessments for Joint Service Installation Pilot Project (JSIPP).

4.2.1.4 AT6 Future Targets

FY 2003 Targets	FY 2004 Targets
Sustain combating CB terrorism technology development and document lessons learned on Force Protection.	Develop after action reports on Joint Service Installation Pilot Project (JSIPP). Refine fixed site facility biological detection CONOPS to reduce life cycle costs.

4.2.2 CB DEFENSE (RDT&E Management Support) (Project CM6 – WMD Civil Support Team)

This funding provides resources to successfully execute the Consequence Management RDA program. WMD-CSTs and U. S. Army Reserve Reconnaissance and Decontamination Teams would receive the systems developed and procured under this program in accordance with the Joint Service Agreement for Chemical and Biological Defense Program Management.

CM6 Actual and Planned Performance

FY2002 Targets	Actual Performance
n/a (FY2003 New Start)	n/a (FY2003 New Start)

4.2.2.4 CM6 Future Targets

FY 2003 Targets	FY 2004 Targets
Support planning and oversight efforts for Inter Agency Board (IAB) to coordinate interagency equipment and operational issues to unsure WMD CST teams interoperability with state and local first responders.	Continue support planning and oversight efforts for IAB to coordinate equipment and operational issues for national WMD-CSTs.
Support planning and operations for 32 WMD CST operations and additional State and national emergency teams. Conduct interagency equipment integration analysis and interoperability studies.	Continue support planning and operations for 32 WMD-CST operations and additional state and national emergency teams.

4.2.3 CB DEFENSE (RDT&E Management Support) (Project DT6 – Joint Doctrine and Training Support)

The activities of this project directly support the Joint Service CB defense program; in particular, the JRO-CBRN, Doctrine and Training (DT), and Modeling & Simulation (M&S). This effort funds (1) development/revision of medical and non-medical Multi-Service and Joint Doctrine and Tactics, Techniques, and Procedures (TTP); (2) development of joint medical, non-medical and M&S requirements; (3) the U. S. Army Chemical School (USACMLS) Joint Senior Leaders' Course (JSLC); (4) assistance in correcting training and doctrine deficiencies covered in General Accounting Office (GAO) reports; (5) support of current and planned NBC Defense studies, analysis, models and simulations, training, exercises, and wargames; determine overlaps, duplication, and shortfalls; and build and execute programs to correct shortfalls in all aspects of NBC Defense.

DT6 Actual and Planned Performance

FY2002 Targets	Actual Performance
Continue to support the development of medical, non-medical and special operations Multi-Service core NBC doctrine; (1) FM 3-11.14 NBC Vulnerability Analysis; (2) FM 3-11.19 MTTP for NBC Reconnaissance and Surveillance; FM 8-284 Treatment of Biological Warfare Agent Casualties. Draft/review joint requirements documents; (1) Joint Biological Standoff Detection System Milestone (MS) III; (2) Joint Protective Air Crew Ensemble MS III; (3) Joint Service Fixed Site Decontamination MS III; (4) Joint Chemical & Biological Agent Water Monitor MS II; (5) Joint Biological Point Detection System (Block 2) MS III; (6) Joint Chemical Environment Survivability Mask MS II; (7) Joint Container Refill System MS II; (8) Automatic Casualty Decontamination System (Draft); (9) Visible Casualty Agent Detection System (Draft). Initiate Collective and Individual Protection Mission Area Analysis. Continue implementation of recommendations provided in the NBC Defense Doctrine and Training Assessment. Provide Service support to implement training review and enhancement initiatives	Continued to support the development of medical, non-medical and special operations Multi- Service core NBC doctrine: (1) NBC Vulnerability Analysis; (2) Potential Military CB Agents and Compounds; (3) Health Service Support in a NBC Environment. Continued to support the integration of CB defense considerations during the revision and development of selected joint doctrinal materials. Continued support to the integration and enhancement of NBC/WMD materials in joint and service professional education. Continued support to the Combatant Commanders with NBC/WMD exercise assistance and training. Coordinated the drafting/review of Joint Operational Requirements Documents (ORDs): (1) Joint Chemical & Biological Agent Water Monitor Milestone (MS) B; (2) Joint Chemical Environment Survivability Mask MS B; (3) Joint Container Refill System MS B; (4) Artemis MS B (Draft); (5) Joint Effects Model MS B (Draft); (6) Joint Operational Effects Federation MS B (Draft); (7) Virtual Prototyping Simulation MS B (Draft); (8) Training Simulation Capability MS B (Draft). Completed assessment of plague and anthrax stockpile. Initiated assessment of Tularemia stockpile requirements.
Continue system requirements analysis; (1) Joint Chemical Agent Monitor; (2) Protective Clothing (JSLIST/FEE/EOD); (3) Joint Protective Air Crew Ensemble	Continued analyses to support the definition phase of the requirements generation process: (1) Completed integrated NBC Contamination Avoidance Mission Area Analysis (MAA); (2) Initiated integrated NBC Contamination Avoidance Mission Needs Analysis (MNA); (3) Initiated Protection (Collective/ Individual) MAA/MNA; (4) Initiated NBC Battle Management MAA/MNA (5) Initiated NBC Decontamination MAA/MNA.
Continue to support additional joint participation in the JSLC	Continued to support additional joint participation in the Joint Senior Leaders' Course (JSLC).
Support Services M&S requirements. Finalize data base tools and integrate CMMS characterizations of the battlespace to ensure a common operational picture. Populate the common data model with existing data and develop missing data. Continue to validate requirements through participation of joint experiments and exercise/war game participation. Verify and document modeling and simulation requirements and tools into C4I systems to optimize Joint CBD operational capability	Supported Services identification and coordination of Battle Management requirements through continued support of the Modeling and Simulations Requirements Panel (MSRP). Continued to validate requirements through support of joint experiments and exercise/war game participation.

DT6 Future Targets

FY 2003 Targets	FY 2004 Targets
Continue to support the development of medical, non-medical and special operations Multi-Service core NBC doctrine: (1) FM 3-11.5 NBC Decontamination; (2) FM 3-11.6 Field Behavior of NBC Agents; (3) FM 4-0.285 Treatment of Chemical Agent Casualties and Conventional Military Chemical Injuries. Continue to support the integration of CB defense considerations during the revision and development of selected joint doctrinal	Continue to support the development of medical, non-medical and special operations Multi-Service core NBC doctrine: (1) NBC Aspects of Consequence Management; (2) NBC Defense of Theater Fixed Sites, Ports, and Airfields. Continue to support the integration of CB defense considerations during the revision and development of selected joint doctrinal materials. Continue support to the integration and enhancement of

FY 2003 Targets	FY 2004 Targets
materials. Continue support to the integration and enhancement of NBC/WMD materials in joint and service professional education. Continue support to the CINCs with NBC/WMD exercise assistance and training. Draft/review Joint Operational Requirements Documents (ORDs): (1) Joint Service General Purpose Mask Milestone (MS) C; (2) Joint CB Agent Water Monitor MS B; (3) Joint Service Mask Leakage Tester MS C; (4) Joint Biological Tactical Detection System MS B; (5) Joint Warning and Reporting Network Block II; (6) Artemis MS B; (7) Joint Effects Model/Joint Ground Effects Model MS B; (8) Joint Operational Effects Federation MS B; (9) Cyanide Pretreatment System (Draft); (10) Joint Biological Agent Identification and Diagnostic System MS B; (11) Smallpox MS BI. Complete assessment of Tularemia stockpile requirements. Initiate Medical NBC Defense Doctrine and Training Assessment.	NBC/WMD materials in joint and service professional education. Continue support to the Combatant Commanders with NBC/WMD exercise assistance and training. Coordinate drafting/review of Joint ORDs.
Continue requirements generation analysis: (1) Initiate Decontamination Mission Area Analysis; (2) Battle Management Mission Area Analysis; (3) Initiate Protection Mission Needs Analysis; (4) Medical Operational Impact Assessment; and (5) Initiate integrated Chemical/ Biological Standoff Detection Analysis of Alternatives (if required).	Continue analyses to support the definition phase of the requirements generation process, joint operational concepts, architecture development, and supporting technical annexes: (1) Toxic Industrial Materials prevalence in Areas of Responsibility on Operations and Tactics for Major Theaters of War and Military Operations other than War; (2) Operational factors affecting protective prophylaxis and pretreatment; (3) Standoff range optimization to support surveillance, reconnaissance, survey, and monitoring capabilities.
Continue to support additional joint participation in the Joint Senior Leaders' Course (JSLC).	Continue to support additional joint participation in the Joint Senior Leaders' Course (JSLC).
Continue support of Services M&S requirements. Finalize effects and behaviors tools for the standardization of the battlespace common operational picture. Define the requirements for simulation based virtual CBD environment for training, mission planning/ rehearsal, force development, and acquisition programs. Validate modeling and simulation requirements and tools for C4I systems.	Continue support of Services Battle Management requirements. Continue to define the requirements for simulation based virtual CBD environment to training, mission planning/rehearsal, force development, and acquisition programs. Validate modeling and simulation requirements and tools for C4I systems.

4.2.4 CB DEFENSE (RDT&E Management Support) (Project DW6 – Dugway Proving Ground)

Project provides the technical capability for testing DoD CB defense materiel, equipment, and systems from concept through production. It finances indirect test operating costs not billable to test customers, to include indirect civilian and contractor labor; repair and maintenance of test instrumentation, equipment, and facilities; and replacement of test equipment. Dugway Proving Ground (DPG), a Major Range and Test Facility Base, is the reliance center for all DoD CB defense testing and provides the United States' only combined range, chamber, toxic chemical lab, and bio-safety level three facility. DPG uses state-of-the-art chemical and life sciences test facilities and test chambers to perform CB defense testing of protective gear, decontamination systems, detectors, and equipment while totally containing chemical agents and biological pathogens. DPG also provides a fully instrumented outdoor range capability for

testing with simulants that can be precisely correlated to the laboratory testing with live agents. Projects programmed for testing at DPG include: Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD), Joint Service Lightweight Nuclear Biological Chemical Reconnaissance System (JSLNBCRS), Joint Service Lightweight Integrated Suit Technology (JSLIST), JSLIST Block II Glove Upgrade, Joint Biological Point Detection System (JBPDS), Joint Chemical Agent Detector (JCAD), Joint Service Sensitive Equipment Decontamination (JSSED), Technical Readiness Evaluation for Biological Standoff Detection Systems, Joint Service General Purpose Mask (JSGPM), Artemis chemical standoff detector, Joint Protective Aircrew Ensemble (JPACE), and Joint Biological Standoff Detection System (JBSDS).

DW6 Actual and Planned Performance

FY2002 Targets	Actual Performance
Provides for civilian labor and other supporting costs that cannot be directly identified to a specific test customer. These civilian personnel perform administration and staff support for DPG's CB test mission to include budget, surety operations, range control, COR duties, and environmental oversight	Provided for civilian labor and other supporting costs that cannot be directly identified to a specific test customer. These civilian personnel performed administration and staff support for DPG's CB test mission to include budget, surety operations, range control, Contracting Officer Representative (COR) duties, and environmental oversight. This account provided the sustaining base for this Nation's highest level of expertise in the area of testing CB defense technologies and equipment.
Provides for labor and supporting costs of contractor personnel performing administration and management of DPG's CB test mission contracts. This is the indirect portion of the total cost of providing contractual effort including chemical analysis, field support, planning, and report documentation. This portion of the contract cannot be specifically identified to a test customer and is funded by indirect funds; the balance which can be directly identified is recouped from customers.	Provided for labor and supporting costs of contractor personnel performing administration and management of DPG's CB test mission contracts. This is the indirect portion of the total cost of providing contractual effort including chemical analysis, field support, planning, and report documentation. This portion of the contract cannot be specifically identified to a test customer and is funded by indirect funds; the balance is recouped from customers.
Provides for a dedicated and specially trained staff to operate and maintain all control systems within DPG's TRIAD Test Complex (Materiel Test Facility, Combined Chemical Test Facility and the Life Science Test Facility).	Provided for a dedicated and specially trained staff to operate and maintain all control systems within DPG's Materiel Test Facility, Combined Chemical Test Facility, and the Life Science Test Facility complex.
Provides for revitalization/modernization efforts at DPG commensurate with technology/facility requirements for future testing. This includes evolving capability needs driven by change in threat and system requirements and equipment purchases to upgrade/replace aging equipment	Provided for revitalization/modernization efforts at DPG commensurate with technology/facility requirements for future testing. Efforts included Synthetic Scene Generator, chemical agent protective materials swatch test fixtures, Detector Test System Modernization, and Fluorescence Aero Particle Sizer.

DW6 Future Targets

FY 2003 Targets	FY 2004 Targets
Provides for civilian labor and other supporting costs that cannot be directly identified to a specific test customer. These civilian personnel perform administration and staff support for DPG's Chemical/ Biological (CB) test mission to include budget, surety operations, range control, COR duties, and environmental oversight. This account provides the sustaining base for this Nation's highest level of expertise in the area of testing chemical and biological defense technologies and equipment.	Provides for civilian labor and other supporting costs that are not directly identifiable to a specific test customer. These civilian personnel perform administration and staff support for DPG's CB test mission to include budget, surety operations, range control, Contraction Officer Representative (COR) duties, and environmental oversight. This account provides the sustaining base for this Nation's highest level of expertise in the area of testing CB defense technologies and equipment.
Provides for labor and supporting costs of contractor personnel performing administration and management of DPG's CB test mission contracts. This is the indirect portion of the total cost of providing contractual effort including chemical analysis, field support, planning, and report documentation. This portion of the contract cannot be specifically identified to a test customer and is funded by indirect funds; the balance is recouped from customers.	Provides for labor and supporting costs of contractor personnel performing administration and management of DPG's CB test mission contracts. This is the indirect portion of the total cost of providing contractual effort including chemical analysis, field support, planning, and report documentation. This portion of the contract cannot be specifically identified to a test customer and is funded by indirect funds; the balance is recouped from customers.
Provides for a dedicated and specially trained staff to operate and maintain all control systems within DPG's TRIAD Test Complex (Materiel Test Facility, Combined Chemical Test Facility, and the Life Science Test Facility).	Provides for a dedicated and specially trained staff to operate and maintain all control systems within DPG's Materiel Test Facility, Combined Chemical Test Facility, and the Life Science Test Facility complex.
Provides for revitalization/modernization efforts at DPG commensurate with technology/facility requirements for future testing. This includes evolving capability needs driven by change in threat and system requirements and equipment purchases to upgrade/replace aging equipment.	Provides for revitalization/modernization efforts at DPG commensurate with technology/facility requirements for future testing. This includes purchases to upgrade/replace aging equipment.

4.2.5 CB DEFENSE (RDT&E Management Support) (Project MS6 – RDT&E Management Support)

This project provides management support for the DoD CB defense program. It includes program oversight and integration of overall medical and non-medical programs by the ATSD(NCB) defense programs through the DATSD(CBD), and the Director, DTRA. Funds execution management is provided by DTRA.

The project also funds Integration of joint requirements, training and doctrine by the JRO-CBRN; Joint Research Development Acquisition (RDA) planning, input to the CB Defense Annual Report to Congress, and Program Objectives Memorandum (POM) Strategy development by the JPEO-CBD.

The project includes programming support for the Joint Service CB Information System (JSCBIS) which serves as a budgetary and informational database for the DoD CB Defense Program. Funding is provided for the CB Archive Information Management System (CBAIMS)—a means to collect, assemble, catalog and archive CB defense information from multiple service locations into a central repository and library.

Funding is also provided for the Joint Test Infrastructure Working Group (JTIWG), which serves as a mechanism to identify, develop, and manage test infrastructure and technology

programs to support Developmental Testing (DT) and Operational Testing (OT) of DoD CB defense systems, as required in the RDA Plan. JTIWG program will fund a series of methodology, instrumentation, and associated validation programs to provide test infrastructure and technologies for testing RDA systems needed to support all services.

Test infrastructure and technology programs have been prioritized in accordance with the RDA Plan and the Draft FY02 Nuclear, Biological, and Chemical (NBC) Joint Priority List (JPL). Programs will be structured to phase highest priority efforts in time to support RDA Plan required tests and schedules to the fullest extent possible.

Test Operating Procedures (TOPs) will be developed to standardize and document new test procedures and/or to update existing test procedures. All test infrastructure and technology programs will be centrally managed and coordinated with the Joint Service community to ensure that all Services' test and acquisition program needs are met.

Chapter 1 of Volume 1 of this report describes the new management organizations. Targets that refer to current organizations may be updated to reflect new organizations as the process and structure is implements during 2003.

MS6 Actual and Planned Performance

FY2002 Targets	Actual Performance
CBAIMS - Archive Chemical and Biological information from multiple service locations	*CBAIMS* - Archived Chemical and Biological information from multiple service locations.
JNBCDB MGT - Provide Joint Nuclear, Biological and Chemical Defense Board (JNBCDB) oversight and analysis for PPBS process	*JNBCDB MGT* - Provided Joint Nuclear, Biological and Chemical Defense Board (JNBCDB) oversight and analysis for the PPBS process.
JSIG MGT - Develop Joint Requirements and conduct milestone reviews. Conduct annual review and update of Joint Modernization Plan, the integrated medical and non-medical Joint Priority List, the JFOCs and the Annual Report to Congress.	*JSIG MGT* - Coordinated the development and milestone reviews of joint CBRN requirements. Conducted annual reviews and updates of the Joint NBC Defense Modernization Plan, the integrated medical and non-medical JPL, the NBC Defense Joint Future Operational Capabilities, and the CB Defense Annual Report to Congress.
JSMG MGT - Develop assessments to support RDA Planning. Provide analytic programmatic support for development of POM Strategy, the Budget Estimate Submit (BES), and the President's Budget (PB) submissions. Respond to specialized evaluation studies throughout the PPBS process.	*JSMG MGT* - Developed assessments to support RDA Planning. Provided analytic programmatic support for development of POM Strategy, the Budget Estimate Submit (BES), and the President's Budget (PB) submissions. Responded to specialized evaluation studies throughout the PPBS process. Provided JSCBIS database management.
OSD MGT - Perform program reviews/assessments, provide programmatic PPBS oversight/analysis, provide congressional issue analysis and support. Supports financial management services provided by the Defense Threat Reduction Agency such as funding distribution and execution reporting. Provide JSCBIS database support.	*OSD MGT* - Performed program reviews/assessments, provided programmatic PPBS oversight/analysis, provided congressional issue analysis and support. Supported financial management services provided by the DTRA such as funding distribution and execution reporting. Provided JSCBIS database support.

MS6 Future Targets

FY 2003 Targets	FY 2004 Targets
CBAIMS - Archived Chemical and Biological information from multiple service locations.	*CBAIMS* - Archived Chemical and Biological information from multiple service locations.
JNBCDB MGT - Provide oversight and analysis for the PPBS process.	*JNBCDB MGT* - Provide oversight and analysis for the PPBS process.

FY 2003 Targets	FY 2004 Targets
JSIG MGT - Plan, coordinate and oversee the development and review of the: Joint CBRN operational requirements generation; DoD CBDP POM Strategy; Joint CBRN Modernization Plan; Integrated medical and non-medical CBRN Joint Priority List; CBRN Joint Future Operational Capabilities, and the CB Defense Annual Report to Congress.	*JSIG MGT* - Plan, coordinate and oversee the development and review of the: Joint CBRN operational requirements generation; DoD CBDP POM Strategy; Joint CBRN Modernization Plan; Integrated medical and non-medical CBRN Joint Priority List; CBRN Joint Future Operational Capabilities, and the CB Defense Annual Report to Congress.
JSMG MGT- Develop assessments to support RDA Planning. Provide analytic programmatic support for development of POM Strategy, the BES, and the PB submissions. Respond to specialized evaluation studies throughout the PPBS process. Provide JSCBIS database management.	*JSMG MGT*- Develop assessments to support RDA Planning. Provide analytic programmatic support for development of POM Strategy, the BES, and the PB submissions. Respond to specialized evaluation studies throughout the PPBS process. Provide JSCBIS database management.
n/a	*JTIWG* - Initiate and conduct test methodology development, test system instrumentation integration, and test technology validation for refereeing agent simulant challenges for field testing (developmental and operational). Initiate planning, modeling, and development of an Interim Chemical Agent Active Standoff Detection Test Fixture.
OSD MGT - Perform program reviews/assessments, provide programmatic PPBS oversight/analysis, provide congressional issue analysis and support. Supports financial management services provided by the DTRA such as funding distribution and execution reporting. Provide JSCBIS database support.	*OSD MGT* - Perform program reviews/assessments, provide programmatic PPBS oversight/analysis, provide congressional issue analysis and support. Supports financial management services provided by the DTRA such as funding distribution and execution reporting. Provide JSCBIS database support.

4.2.6 CB DEFENSE (RDT&E Management Support) (Project O49 – ·Joint Point Test)

The objectives of the Joint Point Test (JPT) program are to plan, conduct, evaluate, and report on joint tests (for other than developmental hardware) and accomplish operational research assessments in response to requirements received from the Combatant Commanders and the Services. This program will provide ongoing input to the Combatant Commanders and Services for development of doctrine, policy, training procedures, and feedback into the Research, Development, Testing & Evaluation (RDT&E) cycle.

O49 Actual and Planned Performance

FY2002 Targets	Actual Performance
Conduct assessments evaluating performance and procedures in a chemical environment. Planned assessment is casualty decontamination procedures	Conducted assessments evaluating performance and procedures in a chemical environment. Conducted assessment on casualty decontamination procedures.
Conduct field trials evaluating performance and procedures in a chemical environment. Field trials to be conducted are casualty decontamination procedures, contamination control and toxic free area operations, and cargo aircraft contamination control	Conducted field trials evaluating performance and procedures in a chemical environment. Conducted casualty decontamination procedures, contamination control and toxic free area operations, and cargo aircraft contamination control in field trials.
Conduct Technical Data Source Book Update. Incremental update of data and information generated from on going Project O49 activity	Updated indexes of test reports and began work on Agent Fate source book.

FY2002 Targets	Actual Performance
Conduct CB Joint Technical Information Center Research. The library responds to inquiries from the field. The new proposed requirements are received by Project O49, and undergoes the following process: Initial Evaluation, Literature Search, and if the request has already been evaluated, a letter response is sent to the requester with the results of the evaluation. If the request has not been examined, further assessment is given to the request to determine if modeling, a field test, a laboratory test, and/or a chamber test is merited.	Responded to command request with literature search to determine droplet sizes of missile-disseminated CB agents.
Conduct laboratory tests evaluating performance and procedures in a chemical environment. Laboratory tests planned will address Live Bio Test on Material Surfaces	Completed test planning. Test support organizations are currently working on solar lighting methods and conditioning chamber.

O49 Future Targets

FY 2003 Targets	FY 2004 Targets
Conduct field trials evaluating performance and procedures in a chemical environment. Field trials to be conducted are in support of operations: (1) determination of chemical droplet size, and (2) processing cargo and troops through an exchange zone.	Conduct assessments, laboratory and field tests evaluating performance and procedures in a chemical and biological environment in support of information requirements submitted by Combatant Commanders and Service representatives.
Conduct laboratory tests evaluating performance and procedures in a chemical environment. Conduct laboratory tests to address the effects of rotor wash on aircrew ensemble.	Conduct field tests evaluating performance and procedures in a chemical environment, to wit, the effectiveness of the C- 17 cargo aircraft in- flight checklist procedure for eliminating smoke and fumes.
Conduct assessments evaluating performance and procedures in a chemical environment. Conduct assessments of the effectiveness of interior building areas for use as chemical rest and relief areas.	Conduct field tests to determine the level of incursion and condensation of chemical warfare agent vapors into tunnels and other underground structures.
Conduct CB Joint Technical Information Center Research. Conduct the following as necessary: Initial Evaluation, Literature Search, or a letter response with the results of the evaluation. Conduct as necessary. further assessment to determine if modeling, a field test, a laboratory test, and/or a chamber test is merited.	Conduct laboratory and field tests evaluating use of cargo covers made from various materials for equipment protection in a chemical or biological environment.
Continue to conduct Technical Data Source Book Update. Continue incremental update of data and information generated from on going Project O49 activity.	Continue to conduct Technical Data Source Book updates by reviewing the literature and updating volumes of the source books with newly published material.

4.2.7 CB DEFENSE (RDT&E Management Support) (Small Business Innovative Research (SBIR))

The purpose of DoD's SBIR program* is to harness the innovative talents of our nation's small technology companies for U.S. military and economic strength. DoD's SBIR program

* As part of its SBIR program, DoD issues an SBIR solicitation twice a year, describing its R&D needs and inviting R&D proposals from small companies -- firms organized for profit with 500 or fewer employees, including all affiliated firms. Companies apply first for a six-month phase I award of $60,000 to $100,000 to test the scientific, technical, and commercial merit and feasibility of a particular concept. If phase I proves successful, the company may be invited to apply for a two-year phase II award of $500,000 to $750,000 to further develop the concept, usually to the prototype stage. Proposals are judged competitively on the basis of scientific, technical, and commercial merit. Following completion of phase II, small companies are

funds early-stage R&D projects at small technology companies -- projects which serve a DoD need and have the potential for commercialization in private sector and/or military markets.

The overall objective of the CBD SBIR program is to improve the transition or transfer of innovative CBD technologies between DoD components and the private sector for mutual benefit. The CBD program includes those technology efforts that maximize a strong defensive posture in a CB environment using passive and active means as deterrents. These technologies include CB detection; information assessment (identification, modeling, and intelligence); contamination avoidance; and protection of both individual soldiers and equipment.

4.2.7.1 SBIR Performance Goal (Outcome). The goal of the CB defense SBIR program is to transfer innovative CBD technologies between DoD components and the private sector for mutual benefit in all areas of CBD research.

4.2.7.2 SBIR Outcome Measure

SBIR is minimally effective when	SBIR is successful when
• Contracts are awarded that demonstrate proof-of-principle or increase scientific understanding of CB defense technology research needs.	• SBIR efforts support the demonstration of technology objectives. • SBIR efforts support the transition of research efforts from the science and technology base to advanced development.

4.2.7.3 SBIR Performance. Since SBIR efforts represent a contracting process rather than a goal in itself, the targets for future years are determined based on the progress of research in ongoing and planned research areas. SBIR topics are updated every six months and reflect a broad range of CBD research activities. During FY02, 34 Phase I SBIR contracts were awarded for CB Defense[**]. During FY01, there were 14 CBD SBIR Topics, 123 Phase I proposals, 18 Phase I awards, and seven Phase II awards. (http://www.dodsbir.net/annualreport/annrpt.html)

4.2.7.4 Assessment of SBIR. CB Defense (CBD) SBIR efforts have been highlighted as a separate category under DoD SBIR Solicitation Topics[*], thus facilitating the process for small businesses and the overall effectiveness of the program.

expected to obtain funding from the private sector and/or non-SBIR government sources (in "phase III") to develop the concept into a product for sale in private sector and/or military markets.

[**] For details, see http://www.dodsbir.net/awardlist/abs021/cbdabs021.htm

[*] See for example http://www.acq.osd.mil/sadbu/sbir/solicitations/sbir031/index.htm.

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